EPA Reg. Jacket 707-313

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 6, 2017

Alexis Chapman
Product Stewardship Regulatory Manager
The Dow Chemical Company
200 Larkin Center
Midland, MI 48674

Subject: Notification per PRN 98-10 – To add coatings and films use statement "Not registered in State of California"
Product Name: SILVADUR ™
EPA Registration Number: 707-313
Application Date: November 16, 2016
Decision Number: 524011

Dear Ms. Chapman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Zebora Johnson at (703) 308-7080 or via email at johnson.zebora@epa.gov.

Sincerely,

John Hebert, Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

SILVADUR™

Long-Lasting Antimicrobial Preservative for Odor Control for use in the Manufacturing of Coatings, Films, Fibers and Foams

NOTIFICATION
707-313
The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:
02/06/2017

Active Ingredient:	
Silver	**2.95%**
Other Ingredients	**97.05%**
Total	**100.0%**

Contains 0.227 lb. active ingredient per gallon

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

READ THE LABELING BEFORE USING
FOR ADDITIONAL INFORMATION SEE BULLETIN

	FIRST AID
IF ON SKIN:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 min. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything to an unconscious person.
HOT LINE NUMBER	
IN CASE OF AN EMERGENCY endangering life or property involving this product, call collect **(989) 636-4400.** Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be necessary.	

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE
CAUSES IRREVERSIBLE EYE DAMAGE
CAUSES SKIN BURNS
HARMFUL IF SWALLOWED
HARMFUL IF ABSORBED THROUGH SKIN

HARMFUL IF INHALED

Do not get in eyes, on skin, or on clothing. Wear protective eyewear. Wear coveralls worn over long-sleeved shirt and long pants, chemical resistant footwear, socks, chemical resistant gloves. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:
Do not allow to freeze

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:
Nonrefillable Container: Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

GENERAL: CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

CONDITIONS OF SALE AND WARRANTY
Notice: Seller warrants that the product conforms to its chemical description as contained on this label and is reasonably fit for the purposes stated on this label when used in accordance with directions under normal conditions of use. THE WARRANTIES MADE IN THIS PARAGRAPH ARE SELLER'S SOLE WARRANTIES AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES.

Manufacture Date: location for date
EPA Reg. No. 707-313
EPA Est. No. establishment number

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SILVADUR™ is a long-lasting antimicrobial preservative for industrial and household products, that when incorporated into materials during the manufacturing process, imparts antimicrobial activity and prevents the growth of bacteria, mold and mildew that may cause unpleasant odors, discoloration, or deterioration of the treated product.

Coatings and Films:
[Not registered for this use in the State of California- optional statement]
Non-food contact uses in industrial and household products such as, water-based paints and coatings for paper and wood coatings, paints used for architectural product finishes, and special-purpose coating. Dose SILVADUR™ to deliver approx. 70 to 1450 ppm of silver (this corresponds to approx. 0.24% to 4.92% by weight of product as supplied in the coating formulation).

Fibers: Non-food contact uses in industrial and household woven and non-woven fibers, such as bedding, apparel, footwear, wall and floor coverings, carpets, draperies, wiping cloths, brushes, filters, insulation, tents, awnings and tarps. Dose SILVADUR™ to deliver approx. 15 to 5000 pm of silver on the fiber (this corresponds to approx. 0.05% to 16.95% by weight of product as supplied in the textile formulation).

Foam:
[Not registered for this use in the State of California- optional statement]
Non-food contact uses in industrial and household Polyurethane foam, such as mop heads, mattresses, mattress pads, pillows, sponges, shoe soles. Dose SILVADUR™ to deliver approx. 30 to 700 ppm of silver in the foam (this corresponds to approx. 0.1% to 2.4% by weight of product as supplied in the foam formulation).

SILVADUR™ weighs 7.7 lbs per gallon

ROHM AND HAAS COMPANY
A Wholly Owned Subsidiary of The Dow Chemical Company
100 Independence Mall West
Philadelphia, PA 19106-2399
Phone: 215-592-3000

The Dow Chemical Company
2301 Larkin Center
1301 Larkin Center Drive
Midland, MI 48674
U.S.A.

November 16, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Julie Chao

RE: SILVADUR™ (EPA Reg. No. 707-313)
Notification of Label Updates

Dear Ms. Chao,

The Rohm and Haas Company, A Wholly Owned Subsidiary of Dow Chemical Company (Dow), wishes to notify US EPA of the following actions for the product SILVADUR™:

- Addition of the California qualifier statement to indicate the Coatings and Films use is not registered in the State of California.

This was inadvertently left off a recent label update.

In order for the application to be processed, the required Notification Statement is included:

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labelling or the confidential statement of formula of this product. I understand that it is violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Enclosed with this letter is EPA Form 8570-1 marked for Notification.

The Dow Chemical Company
200 Larkin Center
1001 Larkin Center Drive
Midland, MI 48674
U.S.A.

Please contact me if you have any questions.

Sincerely,

Alexis L. Chapman

Alexis L. Chapman
Product Stewardship Regulatory Manager
The Dow Chemical Company
200 Larkin Center
Midland, MI 48674
989-633-1933
alexislchapman@dow.com

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
707-313	J. Chao	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
SILVADUR(TM)	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company A Wholly Owned Subsidiary of
The Dow Chemical Company
[redacted]

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[x] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add California qualifier statement to Coatings use.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Alexis Chapman	Prod Stew Sr Reg Spec	989-633-1933

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Alexis Chapman	Prod Stew Sr Reg Spec	
4. Typed Name	**5. Date**	
Alexis Chapman	Nov 16, 2016	DOCUMENTUM

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWO... REDUCTION ACT NOTICE and INS... CTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34). [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FlFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of direction for use", `notification for...". Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 6, 2016

Alexis L. Chapman
Product Stewardship Regulatory Specialist
Rohm & Haas Company
200 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674

Subject: Notification per PRN 98-10 – Add qualifier, update warranty and address
Product Name: SILVADUR™
EPA Registration Number: 707-313
Application Date: May 2, 2016
Decision Number: 517316

Dear Ms. Chapman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Mohammad Alavi at (703) 347-0522 or via email at alavi.mohammad@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

SILVADUR™

Long-Lasting Antimicrobial Preservative for Odor Control for use in the Manufacturing of Coatings, Films, Fibers and Foams

Active Ingredient:

Silver	**2.95%**
Other Ingredients	**97.05%**
Total	**100.0%**

Contains 0.227 lb. active ingredient per gallon

NOTIFICATION

707-313

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

6/6/2016

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

READ THE LABELING BEFORE USING

FOR ADDITIONAL INFORMATION SEE BULLETIN

	FIRST AID
IF ON SKIN:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 min. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything to an unconscious person.
HOT LINE NUMBER	
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NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be necessary.	

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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CAUSES IRREVERSIBLE EYE DAMAGE

CAUSES SKIN BURNS

HARMFUL IF SWALLOWED

HARMFUL IF ABSORBED THROUGH SKIN

HARMFUL IF INHALED

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PHYSICAL AND CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:
Do not allow to freeze

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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GENERAL: CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

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Notice: Seller warrants that the product conforms to its chemical description as contained on this label and is reasonably fit for the purposes stated on this label when used in accordance with directions under normal conditions of use. THE WARRANTIES MADE IN THIS PARAGRAPH ARE SELLER'S SOLE WARRANTIES AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES.

Manufacture Date: location for date
EPA Reg. No. 707-313
EPA Est. No. establishment number

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SILVADUR™ is a long-lasting antimicrobial preservative for industrial and household products, that when incorporated into materials during the manufacturing process, imparts antimicrobial activity and prevents the growth of bacteria, mold and mildew that may cause unpleasant odors, discoloration, or deterioration of the treated product.

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Fibers: Non-food contact uses in industrial and household woven and non-woven fibers, such as bedding, apparel, footwear, wall and floor coverings, carpets, draperies, wiping cloths, brushes, filters, insulation, tents, awnings and tarps. Dose SILVADUR™ to deliver approx. 15 to 5000 pm of silver on the fiber (this corresponds to approx. 0.05% to 16.95% by weight of product as supplied in the textile formulation).

Foam:
[Not registered for this use in the State of California- optional statement]
Non-food contact uses in industrial and household Polyurethane foam, such as mop heads, mattresses, mattress pads, pillows, sponges, shoe soles. Dose SILVADUR™ to deliver approx. 30 to 700 ppm of silver in the foam (this corresponds to approx. 0.1% to 2.4% by weight of product as supplied in the foam formulation).

SILVADUR™ weighs 7.7 lbs per gallon

ROHM AND HAAS COMPANY
A Wholly Owned Subsidiary of The Dow Chemical Company
100 Independence Mall West
Philadelphia, PA 19106-2399
Phone: 215-592-3000

Chao, Julie

From: Chapman, Alexis L (A) <AlexisLChapman@dow.com>
Sent: Thursday, June 02, 2016 11:39 AM
To: Alavi, Mohammad
Cc: Chao, Julie
Subject: RE: EPA Reg. No. 707-313
Attachments: 707-313 SILVADUR 20160502 annotated.pdf; 707-313 SILVADUR 20160502 clean.pdf

Dear Dr. Alavi,

My apologies for this discrepancy.
I have attached updated annotated and clean labels for this product.

Please let me know if these are not sufficient.

Thank you

Alexis L. Chapman
Product Stewardship Senior Regulatory Specialist
Global Regulatory Sciences and Product Sustainability

Dow Microbial Control | The Dow Chemical Company
200 Larkin Center, Midland, MI 48674 USA
phone: 989.633.1933 | email: alexislchapman@dow.com

From: Alavi, Mohammad [mailto:Alavi.Mohammad@epa.gov]
Sent: Thursday, June 02, 2016 10:51 AM
To: Chapman, Alexis L (A)
Cc: Chao, Julie
Subject: EPA Reg. No. 707-313

Dear Ms. Chapman:

I am reviewing your label notification application for EPA Reg. No. 707-313. The label submitted with your application bears an alternate brand name, "Silvadur 900 Antimicrobial." We require that the label bear the primary brand name, i.e., "Silvadur." Please submit a corrected (highlighted) label with the primary brand name so we can proceed with your application. If you have any questions please contact me. Thank you.

Sincerely,

Mohammad R. Alavi, PhD
Antimicrobials Division
Office of Pesticide Programs
(703) 347-0522

Please read instructions on reverse before co ting form. Form Approved. MB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
707-313	J. Chao	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
SILVADUR(TM)	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company A Wholly Owned Subsidiary of
The Dow Chemical Company
[redacted]

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add California qualifier statement, update the Warranty Statement and add address information.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Alexis Chapman	Prod Stew Sr Reg Spec	989-633-1933

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Alexis L Chapman	Prod Stew Sr Reg Spec	Alexis Chapman	May 2, 2016

DOCUMENTUM

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWOI _ REDUCTION ACT NOTICE and INST_ _TIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34). [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FlFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of direction for use", `notification for...". Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only

PRISM Documentum

Inbox
Basic Search
Advanced Search
Categories Search
My Saved Searches
My Checkout
Import Internal
Import External
Log Off

Info Comments Progress

ISB In Processing : 707-313 S985580 2016-05-03
Description: 707-313 S985580 2016-05-03
From: Doc Admin
Received: 5/3/2016 2:21 PM
WorkFlow Instructions:

cd_11332_985580 : Comments

Comment	Author	Date ▲
NON-PRIA NOTIFICATION (Y or N)? Y RESUBMISSION (Y or N)? N FAST TRACK AMENDMENT (Y or N)? N Minor Formulation Amendment (Y or N)? N Other Remarks =	Chambliss, Benjamin	5/3/2016 2:20 PM

Add

Accept

Supporting Docs
- User Guide
- Document Types Guide

The Dow Chemical Company
2030 Larkin Center
1601 Larkin Center Drive
Midland, MI 48674
U.S.A.

May 2, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Julie Chao

RE: SILVADUR™ (EPA Reg. No. 707-313)
Notification of Label Updates

Dear Ms. Chao,

The Rohm and Haas Company, A Wholly Owned Subsidiary of Dow Chemical Company (Dow), wishes to notify US EPA of the following actions for the product SILVADUR™:

- Addition of the California qualifier statement to indicate the Foam use is not registered in the State of California.
- Update to the Warranty Statement
- Addition of address information

In order for the application to be processed, the required Notification Statement is included:

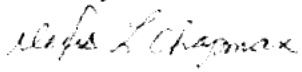
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labelling or the confidential statement of formula of this product. I understand that it is violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Enclosed with this letter is EPA Form 8570-1 marked for Notification.

The Dow Chemical Company
200 Larkin Center
1x01 Larkin Center Drive
Midland, MI 48674
U.S.A.

Please contact me if you have any questions.

Sincerely,



Alexis L. Chapman
Product Stewardship Regulatory Manager
The Dow Chemical Company
200 Larkin Center
Midland, MI 48674
989-633-1933
alexislchapman@dow.com

UNITED S TES ENVIRONMENTAL PROTEC ON AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 29, 2016

Alexis L. Chapman
Product Steward Regulatory Specialist
Rohm and Hass Company (The Dow Chemical Company)
200 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674

Subject: Notification per PRN 98-10 – Add indoor, non-food site
Product Name: Silvadur
EPA Registration Number: 707-313
Application Date: March 18, 2016
Decision Number: 515442

Dear Ms. Chapman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, please contact Jamil Mixon at (703) 308-8032, or via email at mixon.cletis@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

SILVADUR™ 900 Antimicrobial

Long-Lasting Antimicrobial Preservative for Odor Control for use in the Manufacturing of Coatings, Films, Fibers and Foams

Active Ingredient:

Silver.....2.95%

~~Inert~~ Other Ingredients.....97.05%

Total.....100.0%

Contains 0.227 lb. active ingredient per gallon

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

READ THE LABELING BEFORE USING

FOR ADDITIONAL INFORMATION SEE BULLETIN

	FIRST AID
IF ON SKIN:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 min. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything to an unconscious person.
HOT LINE NUMBER	
IN CASE OF AN EMERGENCY endangering life or property involving this product, call collect **(989) 636-4400.** Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be necessary.	

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE

CAUSES IRREVERSIBLE EYE DAMAGE

CAUSES SKIN BURNS

HARMFUL IF SWALLOWED

HARMFUL IF ABSORBED THROUGH SKIN

HARMFUL IF INHALED

NOTIFICATION

707-313

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

4/29/2016

Do not get in eyes, on skin, or on clothing. Wear protective eyewear. Wear coveralls worn over long-sleeved shirt and long pants, chemical resistant footwear, socks, chemical resistant gloves. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:
Do not allow to freeze

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:
Nonrefillable Container: Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

GENERAL: CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

CONDITIONS OF SALE AND WARRANTY
Rohm and Haas warrants that this product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions and as defined under the Directions for Use on this label. ROHM AND HAAS MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES, EITHER OF MERCHANTABILITY OR FITNESS, FOR A PARTICULAR USE. Handling, storage, and use of the product by Buyer or User are beyond the control of Rohm and Haas and Seller. Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow directions will be assumed by the Buyer or User. TO THE EXTENT PREMITTED BY LAW, NEITHER ROHM AND HAAS NOR SELLER SHALL BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT

Manufacture Date: location for date
EPA Reg. No. 707-313
EPA Est. No. establishment number

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SILVADUR™ 900 Antimicrobial is a long-lasting antimicrobial preservative for industrial and household products, that when incorporated into materials during the manufacturing process, imparts antimicrobial activity and prevents the growth of bacteria, mold and mildew that may cause unpleasant odors, discoloration, or deterioration of the treated product.

Coatings and Films: Non-food contact uses in industrial and household products such as, water-based paints and coatings for paper and wood coatings, paints used for architectural product finishes, and special-purpose coating. Dose SILVADUR™ 900 Antimicrobial to deliver approx. 70 to 1450 ppm of silver (this corresponds to approx. 0.24% to 4.92% by weight of product as supplied in the coating formulation).

Fibers: Non-food contact uses in industrial and household woven and non-woven fibers, such as bedding, apparel, footwear, wall and floor coverings, carpets, draperies, wiping cloths, brushes, filters, insulation, tents, awnings and tarps. Dose SILVADUR™ 900 Antimicrobial to deliver approx. 15 to 5000 pm of silver on the fiber (this corresponds to approx. 0.05% to 16.95% by weight of product as supplied in the textile formulation).

Foam: Non-food contact uses in industrial and household Polyurethane foam, such as mop heads, mattresses, mattress pads, pillows, sponges, shoe soles. Dose SILVADUR™ 900 Antimicrobial to deliver approx. 30 to 700 ppm of silver in the foam (this corresponds to approx. 0.1% to 2.4% by weight of product as supplied in the foam formulation).

SILVADUR™ weighs 7.7 lbs per gallon

The Dow Chemical Company
2030 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674
U.S.A.

March 18, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn.: Julie Chao

RE: SILVADUR™, EPA Reg. No. 707-313
Label notification to add indoor, non-food site per PR Notice 98-10

Dear Ms. Chao,

Rohm and Haas Company, a Wholly Owned Subsidiary of The Dow Chemical Company (Dow), hereby submits a label notification for the product SILVADUR™, EPA Reg. No. 707-313. This submission seeks to add Foam use to the currently approved label. Per PR Notice 98-10, we feel the submission is a notification as this use falls under the already approved use patterns industrial and household products and exposure is not expected to increase as the product will be applied using the same method of application and frequency as the currently approved uses, with a lowered use rate range (30-700 ppm).

We have also taken this opportunity to make minor changes for clarity in the Directions for Use and Page one of the label:

- Language has been updated for each use to be clear in dosing instructions, the amount of active being delivered and corresponding percent by weight of product as supplied in the formulation
- The proposed new use was added to the description of the product, under the product name, along with the previously approved uses
- The term "Inert" was changed to "Other" in the label ingredients statement as per PRN 97-6
- In Case Of Emergency phone number was changed

There are no other changes to the currently approved labeling for this product.

The Dow Chemical Company
200 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674
U.S.A.

Included with this letter are the following:

- EPA Form 8570-1 Application for Registration marked for notification
- Proposed label annotated with changes
- Proposed clean label version

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please contact me if you have any questions.

Sincerely,

Alexis L. Chapman

Alexis L. Chapman
Product Stewardship Senior Regulatory Specialist
Dow Microbial Control
The Dow Chemical Company
200 Larkin Center
Midland, MI 48674
989-633-1933
alexislchapman@dow.com

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

ɔd States
Environmental Protection Agency
Washington, DC 20460

[ ] gistration
[ ] Amendment
[x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
707-313	J. Chao	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
SILVADUR(TM)	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company A Wholly Owned Subsidiary of
The Dow Chemical Company
100 Independence Mall W 19019

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add indoor, non-food use per PR Notice 98-10

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	Various	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Alexis Chapman	Prod. Steward Reg. Spec.	989-633-1933

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title
Alexis L Chapman	Prod. Steward Reg. Specialist
4. Typed Name	**5. Date**
Alexis Chapman	Mar 18, 2016

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

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1. Certification with Respect to Citation of Data (EPA Form 8570-34). [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
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4. Five copies of draft labeling;
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Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FlFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of direction for use", `notification for...". Attach a separate page if additional space is needed.

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1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only

UNITED S TES ENVIRONMENTAL PROTE ON AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 18, 2016

Alexis L. Chapman
Product Stewardship Regulatory Manager
Rohm and Haas Company (The Dow Chemical Company)
200 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674

Subject: Notification per PRN 98-10 – Addition of Alternate Brand Name
Product Name: Silvadur
EPA Registration Number: 707-313
Application Date: 3/17/2016
Decision Number: 515664

Dear Ms. Chapman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "SILVADUR 990 PU Antimicrobial" has been added to the product record.

If you have any questions, please contact Jamil Mixon at (703) 308-8032, or via email at mixon.cletis@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

10587/983155 (2)

The Dow Chemical Company

March 17, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Julie Chao

RE: SILVADUR™ (EPA Reg. No. 707-313)
Notification of Alternate Brand Name

Dear Ms. Chao,

The Dow Chemical Company (Dow) wishes to notify US EPA of the following action for the product SILVADUR™:

Addition of the following alternate brand name: SILVADUR™ 990 PU Antimicrobial.

In order for the application to be processed, the required Notification Statement is included:

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labelling or the confidential statement of formula of this product. I understand that it is violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Enclosed with this letter is EPA Form 8570-1 marked for Notification.

Please contact me if you have any questions.

Sincerely,

Alexis L. Chapman
Product Stewardship Regulatory Manager
The Dow Chemical Company
200 Larkin Center
Midland, MI 48674
989-633-1933
alexislchapman@dow.com

Print Form

Please read instructions on reverse before com... ...ing form. Form Approved. ...3 No. 2070-0060

EPA United States Environmental Protection Agency Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. ...mpany/Product Number	2. EPA Product Manager	3. Proposed Classification
...13	J. Chao	[x] None [ ] Restricted
...mpany/Product (Name) SILVADUR(TM)	PM# 33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company A Wholly Owned Subsidiary of The Dow Chemical Company
...

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

...tion of alternate brand name

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	Various	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [x] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

...tact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
...Alexis Chapman	Prod. Steward Reg. Mngr.	989-633-1933

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	5. Date
...Alexis Chapman	Prod. Steward Reg. Mngr.	Mar 17, 2016

...Typed Name ...Alexis Chapman

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DOCUMENT 31

The Dow Chemical Company
200 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674
U.S.A.

March 18, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn.: Julie Chao

RE: SILVADUR™, EPA Reg. No. 707-313
Label notification to add indoor, non-food site per PR Notice 98-10

Dear Ms. Chao,

Rohm and Haas Company, a Wholly Owned Subsidiary of The Dow Chemical Company (Dow), hereby submits a label notification for the product SILVADUR™, EPA Reg. No. 707-313. This submission seeks to add Foam use to the currently approved label. Per PR Notice 98-10, we feel the submission is a notification as this use falls under the already approved use patterns industrial and household products and exposure is not expected to increase as the product will be applied using the same method of application and frequency as the currently approved uses, with a lowered use rate range (30-700 ppm).

We have also taken this opportunity to make minor changes for clarity in the Directions for Use and Page one of the label:

- Language has been updated for each use to be clear in dosing instructions, the amount of active being delivered and corresponding percent by weight of product as supplied in the formulation
- The proposed new use was added to the description of the product, under the product name, along with the previously approved uses
- The term "Inert" was changed to "Other" in the label ingredients statement as per PRN 97-6
- In Case Of Emergency phone number was changed

There are no other changes to the currently approved labeling for this product.

The Dow Chemical Company
200 Larkin Center
1501 Larkin Center Drive
Midland, MI 48674
U.S.A.

Included with this letter are the following:

- EPA Form 8570-1 Application for Registration marked for notification
- Proposed label annotated with changes
- Proposed clean label version

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please contact me if you have any questions.

Sincerely,

Alexis L. Chapman

Alexis L. Chapman
Product Stewardship Senior Regulatory Specialist
Dow Microbial Control
The Dow Chemical Company
200 Larkin Center
Midland, MI 48674
989-633-1933
alexislchapman@dow.com

Please read instructions on reverse before co ing form. Form Approved. MB No. 2070-0060 Print Form

United States Environmental Protection Agency Washington, DC 20460

[ ] Registration [ ] Amendment [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
707-313	J. Chao	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
SILVADUR(TM)	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company A Wholly Owned Subsidiary of The Dow Chemical Company

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[x] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add indoor, non-food use per PR Notice 98-10

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	Various	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [x] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Alexis Chapman	Prod. Steward Reg. Spec.	989-633-1933

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Alexis Chapman	Prod. Steward Reg. Specialist
4. Typed Name	**5. Date**
Alexis Chapman	Mar 18, 2016

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWO. . REDUCTION ACT NOTICE and INST CTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34). [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 **x** 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FlFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of direction for use", `notification for...". Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

The Dow Chemical Company
1500 E. Lake Cook Road
Buffalo Grove, IL 60089

JUL 15 2014

Subject: **SILVADUR ™**
EPA Registration No: 707-313
Application Date: March 27, 2014
Receipt Date: March 31, 2014

Dear Ms. Trueblood:

The following Amendment, submitted under section 3 (c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

Proposed Amendment

- Storage Stability and Container Compatibility Study

Product Chemistry

The Storage Stability is acceptable. Enclosure is the review for the product chemistry review dated 5/29/14.

Based on a review of submitted material and the basic Confidential Statement of Formula (CSF) dated 4/15/2014 and the product label dated 4/28/10 the OPPTS 830.6317 "Storage Stability and 830.6320 "Corrosion Characteristics" studies are acceptable. The results of the two year Storage Stability and corrosion Characteristics Studies show that the concentration of active ingredient is maintained within the range of the certified limits of the active in the product.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

E. Miederhoff

Eric Miederhoff
Acting Product Manager (33)
Regulatory Management Branch I
Antimicrobial's Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

May 29, 2014

DP BARCODE: 419921

MRID: 49351700 and 49351701

SUBJECT: SilvaDur™

REG. NO.: 707-313

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient:
072501	74401-22-4	Silver

TEST LAB: Dow Microbial Control

SUBMITTER: The Dow Chemical Company

GUIDELINE: Product Chemistry

ORGANIZATION: AD\PSB\CTT

REVIEWER: Lynette T. Umez-Eronini

APPROVED BY: Karen P. Hicks

APPROVED DATE: May 29, 2014

COMMENT: This product is for non-food use.

L.T.U.-E.
6/4/2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

May 29, 2014

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 707-313
Product Name: SilvaDur™
DP Barcode: 419921

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Rohm & Haas Co.

CODE: 360 Action Initiated by the Agency;

DATE DUE: June 19, 2014

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Silver	2.95
Inert Ingredient(s):	97.05
Total:	100.0

BACKGROUND:

The Dow Chemical Company has submitted Storage Stability and Corrosion Characteristics studies in support of the registration of an integrated end-use product called SilvaDur™. Prior studies conducted by Rohm & Haas were not found after acquisition of the company by Dow. The product is an antimicrobial preservative for odor control in the manufacturing of coatings, films and fibers. The product is for non-food contact use.

The product chemist reviewed the following documents:

1. Cover letter from Registrant to EPA, 3/27/2014.
2.

49351700	Cover letter same as Transmittal Document, 3/17/2014: Rohm & Haas Company (2014) Submission of Product Chemistry Data in Support of the Registration of SilvaDur. Transmittal of 1 Study.
49351701	Nagahashi, S. (2008) Storage Stability and Container Compatibility of QR-1727. Project Number: 24P/2006/101, GLP/2008/121, GLP/2008/120. Unpublished study prepared by Rohm and Haas Company. 44p.

FINDINGS:

1. Basic CSF, 4/15/2014 and product label, 4/28/2010 are used as references.
2. Storage stability and corrosion characteristics studies were done on test product (sample) stored in high molecular weight high density polyethylene HMWHDPE bottles and double phenolic lined carbon steel (CS) containers for 2 years at 1, 2. 3, 6, 9, 12, 18, and 24 months, at a constant room temperature (CTR) of 75 ± 2 °F and at a 50 ± 2% relative humidity (RH).
3. The active ingredient was determined by titration.
4. Studies using the CS containers were discontinued after 3 months due to the test product being incompatible with the CS containers and causing extreme color changes and deterioration of the said containers.
5. The study was conducted in compliance with U.S. EPA Good Laboratory Practice Standards 40 CFR Part 160.
6. The results of the storage stability and corrosion characteristics studies are shown in the table below:

Summary Table of Storage Stability and Corrosion Characteristics Studies Results

Analysis Time	Average Ag^+, %	Physical Observation of Test Sample	Physical Observation of Test Container	Average Ag Remaining, %
Initial (0 Month)	3.0558	Clear, yellow	---	
1 Month	3.0598 ± 0.0041	Slightly hazy, golden yellow	HMWHDPE: nothing visual; appears normal	100.1309
2 Months	3.0751 ± 0.0122	Slightly hazy, gold	HMWHDPE: slightly discolored on bottom	100.6316
3 Months	3.0817 ± 0.0142	" "	" "	100.8476
6 Months	3.0663 ± 0.0124	" "	" "	100.3426
9 Months	3.0840 ± 0.0298	" "	HMWHDPE: slightly discolored on bottom; noticed flaking of discolored bottom film	101.9228
12 Months	3.0882 ± 0.0181%	" "	" "	101.0603
18 Months	3.0191 +0.1287%	" "	" "	98.7990
24 Months	3.0866 ± 0.0196	" "	" "	101.0079

7. Active — Nominal — Certified Limit
   Silver (formed from silver nitrate) — 2.95 — 2.35 – 3.55
8. The certified limits for the active ingredient meet the EPA Standard Certified Limits.
9. Weight loss from samples during storage due to evaporation of solvent was done by measuring the difference in mass between the container plus sample and the empty container for the sampling times. This showed no significant difference in % content of the active ingredient in the test samples.
10. Titration results show no significant change in the concentration of active ingredient in the product over the 24 months.
11. The physical appearance of the test sample had basically not changed.
12. The physical appearance of the HMWHDPE container after 2 months showed that it was slightly discolored on the bottom throughout the remaining months of the study and at 9 months and thereafter showed flaky discolored film on

the bottom of the bottle (container). However, the physical appearance of the test sample had basically not changed nor had the chemical characteristics of the active ingredient changed.

13. No significant signs of deterioration/leaks were observed in the storage container material during two year storage stability and corrosion characteristics studies.

CONCLUSION:

The results of the two year storage stability and corrosion characteristic studies show that the concentration of active ingredient is maintained within the range of the certified limits for the active in the product. Neither the product nor its packaging showed any significant signs of deterioration. The study provided is found to be acceptable.

The Dow Chemical Company
1500 E. Lake Cook Road
Buffalo Grove, IL 60089
USA

March 27, 2014

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-44501

Re: SILVADUR™ EPA Reg. No. 707-313
Submission of Storage Stability and Container Compatibility Study

Dear Mr. Swindell:

The Dow Chemical Company (Dow) is submitting one study in support of the registration of the silver-containing product, SILVADUR, EPA Reg. No. 707-313.

This study was conducted by Rohm& Haas prior to the acquisition of that company by Dow. This study is the final report for storage stability and container compatibility for EPA Reg. No. 707-313. It is being submitted at this time because I cannot find any record that this study was submitted by Rohm& Haas.

The test material identified in this study is QR-1727, which was the name of the product while still in development.

Included with this letter are the following:

- Transmittal Document
- 3 copies of the study

Please contact me if you have any questions.

Sincerely,

Abigail Trueblood
Product Stewardship Regulatory Manager
847-808-3555
atrueblood@dow.com

TRANSMITTAL BIBLIOGRAPHY OF DATA SUBMITTED IN SUPPORT OF THE REGISTRATION OF SILVADUR™

Submitter: **The Dow Chemical Company for: Rohm& Haas, A Wholly Owned Subsidiary of The Dow Chemical Company**

Regulatory Action: **Submission of one study**

Product Name: **SILVADUR, EPA Reg. No. 707-313**

Test Material Name: **QR-1727**

Study Title	**MRID #**
OPPTS 830.6317 and 830.630.20 Susan L. Nagahashi (2008) U.S. EPA OPPTS 830.6317 and OPPTS 830.6320: Storage Stability And Container Compatibility of QR-1727	**49351701**

Company Official: **Abigail Trueblood**

Signature

Company Name: **The Dow Chemical Company**

Company Contact: **Abigail Trueblood**

847 808 3555

Phone

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Abigail Trueblood
Product Stewardship Regulatory Manager
Dow Chemical Company
1500 E. Lake Cook RD
Buffalo Grove, IL 60089

JUN 10 2014

SUBJECT: Silva Dur
EPA Registration Number: 707-313
Application Dated: March 12, 2014
Receipt Date: March 19, 2014

Dear Ms. Tureblood:

This letter acknowledges receipt of the amendment identified above submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

- CSF revision: Product chemistry data is acceptable.

Based on a review of the submitted Confidential Statement of Formula (CSF), dated 04/15/14 this amendment is acceptable. This formulation will be made part of the record for this file. Should you have any questions concerning this letter, please contact John Cowden at (703) 347-0259.

Sincerely,

John Hebert, Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)

7510P:J.Cowden:6/5/2014:707-313 acceptable CSF

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

April 16, 2014

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 707-313
Product Name: SilvaDur™
DP Barcode: 419045

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/John C. Cowden
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Rohm & Haas Co.

CODE: 362 Formula Change;

DATE DUE: June 17, 2014

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Silver	2.95
Inert Ingredient(s):	97.05
Total:	100.0

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

April 16, 2014

DP BARCODE: 419045

MRID: NA

SUBJECT: SilvaDur™

REG. NO.: 707-313

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient:
072501	74401-22-4	Silver

TEST LAB: Dow Microbial Control

SUBMITTER: The Dow Chemical Company

GUIDELINE: Product Chemistry

ORGANIZATION: AD\PSB\CTT

REVIEWER: Lynette T. Umez-Eronini

APPROVED BY: Karen P. Hicks

APPROVED DATE: April 16, 2014

COMMENT: This product is for non-food use.

L.T.U-E.
4/21/2014

BACKGROUND:

The Dow Chemical Company has submitted an amendment to revise the Confidential Statement of Formula to incorporate changes in production of an integrated end-use product called SilvaDur™. The product is an antimicrobial preservative for odor control in the manufacturing of coatings, films and fibers. The product is for non-food contact use.

The product chemist reviewed the following data package:

1. Cover letter from Registrant to EPA, 3/17/2014.
2. Proposed Basic Confidential Statement of Formula (CSF), 3/6/2014.
3.

49343400	Cover letter same as Transmittal Document, 3/17/2014: Rohm & Haas Company (2014) Submission of Product Chemistry Data in Support of the Amended Registration of SilvaDur. Transmittal of 1 Study.
49343401	Trueblood, A. (2014) SilvaDur: Revised Product Chemistry. Unpublished study prepared by Dow Microbial Control. 15p.

4. Basic CSF, 4/15/2014.

FINDINGS:

1. Basic CSF, 3/14/2014 is obsolete and is superseded by Basic CSF, 4/15/2014.
2. Product label, 4/28/2010 is used as a reference.
3. The nominal concentration of the active ingredient on Basic CSF, 4/15/2014 is consistent with the product label.
4. Support is provided in the cover letter for changes in the upper and lower certified limits of the inert ingredients and is acceptable.
5. Wider certified limits for the [redacted] are acceptable, while all other inert ingredients meet EPA standard certified limits.
6. Revised product chemistry data (see MRID 49343401) supports OPPTS 830.1550, 830.1620; and 830.1750; in general, addresses OPPTS 830.1600 and 830.1670 Discussion of formation of impurities to correspond with proposed changes in the production of the integrated end-use product in this submission.

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Group A product chemistry data have been upgraded and met. The Basic CSF, 4/15/2014 is acceptable and supersedes all previous Basic CSFs.

Inert ingredient information may be entitled to confidential treatment

March 17, 2014

The Dow Chemical Company
1500 E. Lake Cook Road
Buffalo Grove, IL 60089
USA

Mr. Marshall Swindell (PM 33)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: SILVADUR™, EPA Reg. No. 707-313
Amended Product Chemistry/ Revised Confidential Statement of Formula (CSF)

Dear Mr. Swindell:

The Dow Chemical Company (Dow) hereby submits an application to amend the product chemistry for SILVDUR (EPA Reg. No.707-313). This product registration is held by the Rohm& Haas Company, however Rohm & Haas is a wholly owned subsidiary of The Dow Chemical Company.

Specifically, this amendment seeks to accomplish the following:

- Revise the CSF to incorporate production improvements and make minor corrections
- Update the product chemistry package to conform with the proposed CSF

The primary change being proposed to the currently approved CSF will change the nominal concentrations and ranges for [redacted], [redacted], and [redacted] These changes are being proposed based on the following:

[redacted]

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

[redacted]

A proposed revision for the Product Chemistry sections OPPTS 830.1550; 830.1620, and 830.1750 to correspond to these proposed changes is included in this submission.

There are a few corrections and updates to the existing CSF which have been included as well:

- The registrant name has been corrected to show the current legal status of Rohm & Haas Company
- The list of production sites has been updated to include sites which may produce, relabel and/ or repackage this material
- The EPA Registration Number has been added
- The active ingredient has been described as Silver (Formed from silver nitrate); this change is consistent with the description of active ingredient for EPA Reg. No. 464-783 and 464-785
- The CAS number for the active ingredient has been corrected and EPA Chemical Code removed
- CAS numbers have been added for the [redacted] and both have been identified by chemical name
- The lower limits for the [redacted] impurities have been removed

The changes proposed in this submission do not affect the toxicological profile for this product in any way. Nor is there any substantial change in its physical properties.

Enclosed with this cover letter are the following:

- EPA Form 8570-1 Marked for Amendment
- Two copies of the proposed CSF
- Three copies of the proposed revised product chemistry
- Transmittal document

Please contact me if you have any questions.

Sincerely,

Abigail Trueblood
Product Stewardship Regulatory Manager
847-808-3555
atrueblood@dow.com

Print Form

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] **Registration**
[ ] **Amendment**
[ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
707-313	Mr. Marshall Swindel	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
SilvaDur™	33	

5. Name and Address of Applicant *(Include ZIP Code)*
Rohm and Haas Company, A Wholly Owned Subsidiary of The Dow Chemical Company
100 Independence Mall West;Philadelphia, PA 19106-2399

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to revise CSF and product chemistry for SILVADUR(TM), 707-313

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [X] Other (Specify) HDPE
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	Various	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [X] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Abigail Trueblood	Product Stewardship Regulatory Manager	847-808-3555

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
[signature]	Product Stewardship Regulatory Manager
4. Typed Name	**5. Date**
Abigail Trueblood	March 17. 2014

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Co

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 11 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Abigail Trueblood
Product Stewardship Manager for,
The Dow Chemical Company
1500 East Lake Cook Road
Buffalo Grove, IL 60089

Subject: SilvaDur ™
EPA Registration Number 707-313
Your Notification Dated March 9th, 2012
EPA Received Date March 12th, 2012

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add an additional brand name, " SilvaDur ™ 900 Anitmicorbial", is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

March 9, 2012

The Dow Chemical Company
1500 E. Lake Cook Road
Buffalo Grove, IL 60089
USA

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Marshall Swindell/ PM 33

Re: SILVADUR™ EPA Reg. No. 707-313
Notification of an Alternate Brand Name

Dear Mr. Swindell:

The Dow Chemical Company (Dow), on behalf of our wholly owned subsidiary Rohm& Haas Company wishes to submit an alternate brand name for SILVADUR, EPA Reg. No. 707-313.

The alternate brand name being notified is:

SilvaDur™ 900 Antimicrobial

In order for the application to be processed, the required Notification Statement is below:

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Enclosed with this letter is EPA Form 8570-1, marked for Notification.

Please contact me with any questions using the contact information below.

Sincerely,

Abigail Trueblood
Product Stewardship Manager
The Dow Chemical Company
1500 East Lake Cook Road
Buffalo Grove, IL 60089
847-808-3555
atrueblood@dow.com

Print Form

Please read instructions on reverse before completing form. Approved. OMB No. 2070-0060. Approval expires 2-28-

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] **Registration**
- [ ] **Amendment**
- [x] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
707-313	M. Swindell	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
SILVADUR	33	

5. Name and Address of Applicant *(Include ZIP Code)*
Rohm& Haas Company,A Subsidiary of The Dow Chemical Company
100 Independence Mall West
[redacted]
[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of an alternate brand name

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) HDPE
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	Various	[x] On Label [ ] On Labeling accompaning product

6. Manner in Which Label is Affixed to Product [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Abigail Trueblood	Product Stewardship Manager	847-808-3555

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
[signature]	Product Stewardship Manager
4. Typed Name	**5. Date**
Abigail Trueblood	3-9-12

EPA Form 8570-1 (Rev. 2-94) Previous editions are obsolete White - EPA File Copy (original) Yellow - Applicant Co

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 2 8 2010

Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106-2399

Attention: Valerie Phillips
Regulatory Manager

Subject: SilvaDur™ Anitmicrobial Preservative
EPA Reg. No. 707-313
Amendment Application Date: January 30, 2010
EPA Received Date: February 2, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. The Agency has no objection to the following:

- Updating label requirements for Storage Container Disposal (PR Notice 2007-4)
- Add an emergency contact number
- Updating First Aid Language

A stamped label is included with this letter for your records. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

SilvaDur™

Long-Lasting Antimicrobial Preservative for Odor Control for use in the Manufacturing of Coatings, Films and Fibers

ROHM AND HAAS
100 INDEPENDENCE MALL WEST
PHILADELPHIA, PA 19106
TELEPHONE: (215) 592-3000

ACTIVE INGREDIENT:		
Silver		**2.95%**
INERT INGREDIENTS:		**97.05%**
	Total:	**100.0%**

Contains 0.227 lb. active ingredient per gallon

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

READ THIS LABELING BEFORE USING
FOR ADDITIONAL INFORMATION SEE BULLETIN

IF ON SKIN:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 min.
- Call a poison control center or doctor for treatment advice.

IF IN EYES:
- Hold eye open and rinse slowly and gently with water for 15-20 min.
- Remove contact lenses, if present, after first 5 min. then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF INHALED:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to- mouth if possible.
- Call a poison control center or doctor for further treatment advice.

IF SWALLOWED:
- Call a poison control center or doctor immediately for treatment advice.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Have person sip a glass of water if able to swallow. Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IN CASE OF EMERGENCY CALL ROHM AND HAAS COMPANY 215-592-3000

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be necessary.

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE
CAUSES IRREVERSIBLE EYE DAMAGE
CAUSES SKIN BURNS
HARMFUL IF SWALLOWED
HARMFUL IF ABSORBED THROUGH SKIN
HARMFUL IF INHALED

Do not get in eyes on skin or on clothing. Wear protective eyewear. Wear Coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, chemical-resistant gloves. Avoid breathing vapor or spray mist. Wash thoroughly with soap and

water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS
This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS
Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL
PESTICIDE STORAGE
Do not allow to freeze.

PESTICIDE DISPOSAL
Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL
Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

GENERAL
CONSULT FEDERAL, STATE, OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES

CONDITIONS OF SALE AND WARRANTY
Rohm and Haas warrants that this product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions and as defined the Directions for Use on this label. ROHM AND HAAS MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES, EITHER OF MERCHANTABILITY OR FITNESS, FOR A PARTICULAR USE. Handling, storage, and use of the product by Buyer or User are beyond the control of Rohm and Haas and Seller. Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow directions will be assumed by the Buyer or User. TO THE EXTENT PERMITTED BY LAW, NEITHER ROHM AND HAAS NOR SELLER SHALL BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT

Date of Manufacture: location for date
EPA Reg. No. 707-313
EPA Est. No. establishment number

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SilvaDur™ is a long-lasting antimicrobial preservative for industrial and household products, that when incorporated into materials during the manufacturing process, imparts antimicrobial activity and prevents the growth of bacteria, mold and mildew that may cause unpleasant odors, discoloration or deterioration of the treated product.

Coatings and Films: Non-food contact uses in industrial and household products such as, water-based paints and coatings for paper and wood coatings, paints used for architectural product finishes, and special-purpose coatings. Use SilvaDur™ at a rate of 0.24% to 4.92% (70 to 1450 ppm active ingredient).

Fibers: Non-food contact uses in industrial and household woven and non-woven fibers such as bedding, apparel, footwear, wall and floor coverings, carpets, draperies, wiping cloths, brushes, filters, insulation, tents, awnings and tarps. Use SilvaDur™ in the treatment bath to provide 0.0015% to 0.5% (15 and 5000 ppm) silver on the fiber.

SilvaDur™ weighs 7.7 lbs per gallon

ACCEPTED
with COMMENTS
EPA Letter Dated:
APR 28 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 707-313

ROHM AND HAAS

ROHM AND HAAS COMPANY
SPRING HOUSE TECHNICAL CENTER, 727 NORRISTOWN ROAD, P.O. BOX 904, SPRING HOUSE, PA 19477-0904 USA
TELEPHONE: (215) 641-7000 FAX: (215) 619-5001

January 30, 2010

Document Processing Desk 7502P (E-SUB)
U.S. EPA – Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: Marshall Swindell (PM 33)

Subject: SilvaDur™ Antimicrobial Preservative
EPA Reg. No. 707-313
Label Amendment per PR Notice 2007-4

Dear Mr. Swindell,

Please find enclosed an application to amend the label for the Rohm and Haas Company Product SilvaDur™ Antimicrobial Preservative (EPA Reg. No 707-313).

The purpose of the amendment is to:

- update label with the requirements of PR Notice 2007-4 "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment"
- add an emergency contact number (previously requested by EPA)
- align the First Aid and Precautionary Statement sections for label consistency

Once approved I am requesting a new stamped label.

Administrative items included to support this amendment are as follows:

1. Application form # 8570-1
2. Five (5) paper copies of proposed label
3. CD containing copy of proposed label
4. Certification with Respect to Label Integrity

Please contact me with questions regarding this submission.

Sincerely,

Valerie T. Phillip
Regulatory Specialist
DMC
215-641-7696

/enclosures

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Rohm and Haas Co. / 707-313	Mr. Marshall Swindell	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Rohm and Haas Co. / SilvaDur (tm)	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106-2399

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add Label Language per PR Notice 2007-4.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes	[ ] Yes	[ ] Yes	[ ] Metal
[X] No	[X] No	[X] No	[X] Plastic
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	[ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5, 22, 220 Liter	on label

6. Manner in Which Label is Affixed to Product: [X] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Valerie T. Phillip	Regulatory Specialist	215.641.7696

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Valerie D. Phillip	Regulatory Specialist
4. Typed Name	**5. Date**
Valerie T. Phillip	January 30, 2010

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
707-313	January 30, 2010	000707-00313.20091019.PRN2007-4 AMEND SilvaDur

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Valerie D. Phillip
Signature

January 30, 2010
Date

Valerie T. Phillip
Name (typed)

Regulatory Specialist
Title

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

AUG 2 0 2009

James Hagan
Rohm & Hass
100 Independence Mall West
Philadelphia, PA 19106

Subject: Inquiry Into the Possible Presence of Silver Measuring Between 1 and approximately 100 Nanometers in Registered, Silver-Based Pesticide Products

Dear Mr. Hagan:

The United States Environmental Protection Agency (EPA) understands that some registered silver-based pesticide products may contain silver in a form that is measurable in nanometers. For purposes of this particular letter and request, EPA is specifically interested in determining if your silver-based pesticide product contains any amount of silver in any form having a dimension that measures between 1 and approximately 100 nanometers [hereinafter referred to as "nanosilver"]. Please be advised that the specified size range is subject to change in the future as new information becomes available. Accordingly, the Agency reserves the right to revisit and change the specified size range if necessary.

Your company has the following currently registered silver product(s):

Registration Number	Registration Name
707-313	Silva Dur

The Agency is requesting the following information from the product(s) listed above:

- A statement as to whether (or not) your registered, silver-based pesticide product(s) contain(s) any amount of nanosilver.

- If your product(s) does/do contain nanosilver, any existing information not previously provided to the Agency that characterizes the size and size distribution of such silver as measured in nanometers, as well as any information not

previously provided to the Agency that describes the manufacturing process used to produce the silver in the size range specified above.

- If your product(s) is/are to be used for an end-use formulation that contain(s) a composite (the active ingredient comprised of nanosilver, plus a carrier [e.g., silica or sulfur], that forms a matrix complex), any existing information not previously provided to the Agency that characterizes the size and size distribution of the composite.

- If your product(s) does/do contain nanosilver, any existing information not previously provided to the Agency that addresses the effects of exposure to the nanosilver on humans or nontarget species, and/or on the levels of potential human and environmental exposure.

Please note that it is EPA's position that the information requested above is reportable under FIFRA section 6(a)(2), which requires the reporting of any factual information regarding unreasonable adverse effects on the environment. As codified in EPA's regulations setting forth the reporting requirements for risk/benefit information under section 6(a)(2), registrants are required to submit information:

> "if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product."

40 CFR §159.195(a).

In accordance with your FIFRA section 6(a)(2) obligation, therefore, EPA seeks receipt of the information set forth above, to the extent you have such information, within 30 days from the date of receipt of this letter. Please note that a failure to comply with the requirements of FIFRA section 6(a)(2) is considered a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N), and could result in actions for civil penalties and/or criminal penalties under FIFRA section 14.

If you have any questions concerning this letter, please contact Marshall Swindell at (703) 308-6341 or Demson Fuller at (703) 308-8062.

Sincerely,

Joan Harrigan Farrelly

Joan Harrigan-Farrelly, Director
Antimicrobials Division
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 21 2008

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106-2399

Attention: Valerie Phillips

Subject: SilvaDur
EPA Registration No. 707-313
Notification Dated January 23, 2008

This will acknowledge receipt of your notification for the following additional alternate brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

ADDITIONAL BRAND NAME

"SilvDur ET"

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Martha A. Terry /for

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

ROHM AND HAAS

ROHM AND HAAS COMPANY
SPRING HOUSE TECHNICAL CENTER, 727 NORRISTOWN ROAD, P.O. BOX 904, SPRING HOUSE, PA 19477-0904 USA
TELEPHONE: (215) 641-7000 FAX: (215) 641-7857

NOTIFICATION

January 23, 2008

Mr. Marshall Swindell (PM33)
Antimicrobial Division
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Subject: SilvaDur™
EPA Registration No. 707-313
Additional Brand Name Notification

Dear Mr. Swindell:

Pursuant to 40 CFR 152.46 (a)(2), we hereby notify the U.S. Environmental Protection Agency of the additional brand name, "SilvaDur™ ET Antimicrobial" (EPA Reg.No.707-313).

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is violation of 18 USC Section 1001 to willfully make any false statement to USEPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Thank you for handling this notification. Please feel free to contact me if you have any questions regarding this request.

Sincerely,

Valerie T. Phillip
Regulatory Specialist
Process Chemicals & Biocides
(215) 641-7696

/enclosures

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Rohm and Haas Co. / 707-313	Mr. Marshall Swindell	[X] None [ ] Restricted
4. Company/Product (Name) Rohm and Haas Co. / SilvaDur(TM)	PM# 33	
5. Name and Address of Applicant *(Include ZIP Code)* Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19106-2399 [ ] *Check if this is a new address*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [X] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add Additional Brand Name - "SilvaDur(tm) ET Antimicrobial"

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5, 22, 220, Liter	on label

6. Manner in Which Label is Affixed to Product [x] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Valerie T. Phillip	Regulatory Specialist	215.641.7696

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Valerie D. Phillip	Regulatory Specialist
4. Typed Name	5. Date
Valerie T. Phillip	January 23,2008

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DEC 13 2007

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106-2399

Attention: Valerie Phillips

Subject: SilvaDur
EPA Registration No. 707-313
Notification Dated November 13, 2007

This will acknowledge receipt of your notification for the following additional alternate brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

ADDITIONAL BRAND NAME

"SilvDur ET"

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

ROHM AND HAAS

ROHM AND HAAS COMPANY
SPRING HOUSE TECHNICAL CENTER, 727 NORRISTOWN ROAD, P.O. BOX 904, SPRING HOUSE, PA 19477-0904 USA
TELEPHONE: (215) 641-7000 FAX: (215) 641-7857

NOTIFICATION

November 13, 2007

Mr. Marshall Swindell(PM33)
Antimicrobial Division
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Subject: SilvaDur™
EPA Registration No. 707-313
Additional Brand Name Notification

Dear Mr. Swindell:

Pursuant to 40 CFR 152.46 (a)(2), we hereby notify the U.S. Environmental Protection Agency of the additional brand name, "SilvaDur™ ET" (EPA Reg.No.707-313).

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is violation of 18 USC Section 1001 to willfully make any false statement to USEPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Thank you for handling this notification. Please feel free to contact me if you have any questions regarding this request.

Sincerely,

Valerie T. Phillip
Regulatory Specialist
Process Chemicals & Biocides
(215) 641-7696

/enclosures

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Rohm and Haas Co. / 707-313	Mr. Marshall Swindell	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Rohm and Haas Co. / SilvaDur(tm)	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Rohm and Haas Company
727 Norristown Road
P.O. Box 904
Spring House, PA 19477

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[X] Notification - Explain below.

[ ] Final printed labels in repsonse to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add Additional Brand Name - "SilvaDur(tm) ET"

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5,22,220 Liter	on label

6. Manner in Which Label is Affixed to Product [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Valerie T. Phillip	Regulatory Specialist	215.641.7696

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Valerie T. Phillip	Regulatory Specialist
4. Typed Name	**5. Date**
Valerie T. Phillip	November 13, 2007

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106-2399

Attention: Valerie Phillips

Subject: SilvaDur
EPA Registration No. 707-313
Notification Dated November 13, 2007

This will acknowledge receipt of your notification for the following additional alternate brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

ADDITIONAL BRAND NAME

"SilvDur ET"

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_x_ Registration
__ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
707-313	

Term of Issuance: Unconditional

Name of Pesticide Product: SilvaDur™

Name and Address of Registrant (include ZIP Code):

Rohm and Haas Company
Spring House Technical Center
727 Norristown Road
Spring House, PA 19477-0904

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 707-313."

Signature of Approving Official:

Marshall Swindell
Product Manager-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: AUG 23 2007

EPA Form 8570-6

The Confidential Statement of Formula dated August 8th, 2007, is acceptable.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

SilvaDu.™

Long-Lasting Antimicrobial Preservative for Odor Control for use in the *Manufacturing of Coatings, Films and Fibers*

ROHM AND HAAS
100 INDEPENDENCE MALL WEST
PHILADELPHIA, PA 19106
TELEPHONE: (215) 592-3000

Lot Number
( )

ACTIVE INGREDIENT:		
Silver		2.95%
INERT INGREDIENTS:		97.05%
	Total:	100.0%

Contains 0.227 lb. active ingredient per gallon

KEEP OUT OF REACH OF CHILDREN

DANGER

READ THIS LABELING BEFORE USING
FOR ADDITIONAL INFORMATION SEE BULLETIN

IF IN EYES:
- Hold eye open and rinse slowly and gently with water for 15-20 min. Remove contact lenses, if present, after first 5 min. then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15- 20 min.
- Call a poison control center or doctor for advice.

IF INHALED:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth.
- Call a poison control center or doctor for advice.

IF SWALLOWED:
- Call a poison control center or doctor immediately for advice.
- Do not induce vomiting unless told to do so by a poison control center or doctor..
- Have person sip a glass of water if able to swallow.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be necessary.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE
CAUSES IRREVERSIBLE EYE DAMAGE
CAUSES SKIN BUNS
HARMFUL IF SWALLOWED
HARMFUL IF ABSORBED THROUGH SKIN
HARMFUL IF INHALED

Do not get in eyes on skin or on clothing. Wear protective eyewear. Wear Coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, chemical-resistant gloves. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. .

ENVIRONMENTAL HAZARDS
This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS
Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL
PESTICIDE STORAGE
Do not allow to freeze.

PESTICIDE DISPOSAL
Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL
Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Avg. Gross: LB KG
Net: LB KG
Avg. Tare: LB KG

Product Code (91)

«LN1»

Container: Code Number «SN1»

Label Number 9 April 2007

IRECTIONS FOR USE

is a violation of Federal law to use this product in a manner inconsistent with its beling.

---

lvaDur™ is a long-lasting antimicrobial preservative for industrial and household oducts, that when incorporated into materials during the manufacturing process, imparts itimicrobial activity and prevents the growth of bacteria, mold and mildew that may cause ıpleasant odors, discoloration or deterioration of the treated product.

oatings and Films: Non-food contact uses in industrial and household products such as, ater-based paints and coatings for paper and wood coatings, paints used for architectural oduct finishes, and special-purpose coatings. Use SilvaDur™ at a rate of 0.24% to 4.92% 0 to 1450 ppm active ingredient).

bers: Non-food contact uses in industrial and household woven and non-woven fibers ch as bedding, apparel, footwear, wall and floor coverings, carpets, draperies, wiping oths, brushes, filters, insulation, tents, awnings and tarps. Use SilvaDur™ in the treatment th to provide 0.0015% to 0.5% (15 and 5000 ppm) silver on the fiber.

vaDur™ weighs 7.7 lbs per gallon

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 23 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

707-313

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

08/07/07

DP BARCODE:	340170	
MRID:	471090-01	
SUBJECT:	SilvaDur™	
REG. NO. OR FILE SYMBOL:	707-GRG	
DOCUMENT TYPE:	Product Chemistry Review	
Manufacturing-use [X] OR	End-use Product []	
INGREDIENTS (PC Codes)	Silver (072501)	
CAS Number:	(14701-21-4)	
TEST LAB:	SafePharm Laboratories Ltd	
SUBMITTER:	Rohm and Haas Company	
GUIDELINE:	830 Group A & B	
COMMODITIES:	Formulation	
REVIEWER:	Krishna K. Deb	ORGANIZATION: AD
APPROVER:	Karen P. Hicks	APPROVED DATE:
COMMENT:		August 8, 2007

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

07/10/2007

TO: Marshall Swindell / Karen Leavy
PM Team 33

FROM: Krishna K. Deb, Chemist 8/8/07
Product Science Branch, CT Team
Antimicrobial Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510C)

APPLICANT: Rohm and Haas Company
Action code: A54
Due date: 09/05/2007

Product Formulation
Active Ingredient(s)

	% by Wt
Silver.....	....2.95
INERT INGREDIENTS ----------	97.05
Total	100.00

BACKGROUND:

Rohm and Haas Company submitted an application for registration of a new integrated end-use product, SilvaDur™ (known also as QR-1727). This product is an antimicrobial preservative (odor control) for industrial and household to prevent the growth of bacteria, mold and mildew. The registrant provided a Confidential Statement of Formula (CSF) for the basic formulation (dated April 3, 2007).

FINDINGS:

Group A Requirements – Product Chemistry, QR-1727, Manufacturing-Use Product (MRID 471090-01)

- Group A product chemistry data requirements applicable to manufacturing-use products have been met.

Group B Requirements – Product Chemistry, QR-1727, Manufacturing-Use Product (MRID 471090-01)

- Group B product chemistry data requirements applicable to manufacturing-use products have been met, with the exception of 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics).
- Good Laboratory Practices (GLP) statements were provided stating that the studies performed by the Rohm and Haas Company and SafePharm Laboratories Ltd. were conducted in compliance with U.S. EPA, FIFRA GLP standards and UK GLP Standards, respectively

Confidential Statement of Formula

- The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient (s) given in the revised Basic CSF agreed with the percentages declared on the product label.
- The certified limits for the active and inert ingredients given in the revised CSF were acceptable.
- All the active and inert ingredients are EPA registered for use in nonfood products.

Product Label

- The label ingredient statement, which lists the nominal concentration of the active ingredient, is consistent with information contained on the CSF.

- Certain information on the product label needs to be corrected, as follows:

- Change "CAUSES SKIN BUNS" to read "CAUSES SKIN BURNS" in the "Precautionary Statements" section of the label.

- Under the "Physical and Chemical Hazards" section of the label, add the following (or a similar) statement: "The product is not compatible with water and moderate reducing agents such as zinc."

- Change the typeset of "STORAGE AND DISPOSAL" to be the same as the typeset of the child hazard warning.

- Change "in a sanitary landfill by incineration" to read "in a sanitary landfill, or by incineration" in the "Container Disposal" section of the label.

The label could be further improved by adding instructions to the "Pesticide Storage" section that specify what to do if the product leaks or spills from its container

RECOMMENDATIONS:

To satisfy 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics) requirements, the applicant must provide results for a minimum of 1 year from a GLP-compliant study. Results for interim studies (i.e., 3 months) were provided. Testing of the product and packaging is continuing. Storage and disposal information on the product label needs to be revised if product composition (or packaging) deteriorates over time.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [X] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: 707-GRG_____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [X]

Note: The product is not for food use.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No []

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Silver	2.95	2.35	3.55

Note: The applicant proposed certified limits for the active ingredient that differ from the standard limits, due to the limitations of the manufacturing process. The basis of the proposed limits appears sound and complete.

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [X] No [] Not applicable [ ]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [X] No [ ] Not applicable [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	471090-01
830.1600 Description of Materials	A	471090-01
830.1620 Production Process[2]	A	471090-01
830.1650 Formulation Process[3]	NA – The active ingredient is silver (from silver nitrate).	
830.1670 Formation of Impurities[4]	A	471090-01
830.1700 Preliminary Analysis[5]	A – The applicant provided preliminary analysis results for 5 different batches of the product.	471090-01
830.1750 Certified Limits[6]	U – The applicant proposed certified limits for the active ingredient that differ from the standard limits. The basis of the proposed limits appears sound and complete	471090-01
830.1800 Analytical Method[7]	A – A copy of a titration method was provided.	471090-01
830.1900 Submittal of Samples	[Samples are to be provided on a case-by-case basis for manufacturing-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	At 20.0±0.5°C, the color of the product is yellow/ orange by visual assessment and 5Y 8.5/8 by the Munsell Color System.	471090-01
830.6303 Physical State	A	At 20.0±0.5°C, the product is a transparent liquid with no precipitation or sedimentation.	471090-01
830.6304 Odor	A	At 20.0±0.5°C, the product has a strong ammonium odor by nasal inhalation.	471090-01
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	Not required for manufacturing-use products.	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Temperature increases were observed on the addition of water and on the addition of the reducing agent zinc powder. The results indicate that the product is not compatible with water and moderate reducing agents such as zinc phosphate or kerosene. The temperature increase observed upon the addition of 0.1M potassium permanganate was attributed to the presence of water in the potassium permanganate solution.	471090-01
830.6315 Flammability/ Flame Extension	A	The flashpoint of the product was reported to be 16±2°C (61°F; using a closed cup equilibrium method; Method A9 of Commission Directive 92/69/EEC).	471090-01
830.6316 Explodability	A	The product is not explosive at pH 11.4, 11.7, and 12.0 (using Method A14 of Commission Directive 92/69/EC).	471090-01
830.6317 Storage Stability	A	Interim storage stability study results were provided for the following conditions: storage for 3 months at 24±1°C at 50% relative	471090-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		humidity in two types of containers (i.e., high molecular weight HDPE and double phenolic-lined carbon steel). The relative change of the active ingredient was +0.85% in the HDPE container, and -1.08% in the other container. The product color changed from clear yellow to hazy gold, regardless of the container type. Note: Studies using the carbon steel container have been discontinued. See 830.6320.	
830.6319 Miscibility[1]	A	The product is not an emulsifiable liquid. The product does not bear instructions for dilution with petroleum solvents.	471090-01
830.6320 Corrosion Characteristics	A	Interim corrosion characteristics study results were provided for the following conditions: storage for 3 months at 24±1°C at 50% relative humidity in two types of containers The HDPE container appears to be acceptable; studies are continuing. Changes to the carbon steel container included discoloration, peeling, and blistering of the lining after only 1 month of storage. The carbon steel container is not recommended for storage or shipping of the product.	471090-01
830.6321 Dielectric Breakdown Voltage	NA	Not required for manufacturing-use products.	
830.7000 pH[2]	A	The mean pH of the product was reported to be 9.55 at 25°C (using a procedure based on CIPAC Method MT75). A 1% aqueous dispersion of the product was used.	471090-01
830.7050 UV/Visible Absorption	NA	Not required for manufacturing-use products.	
830.7100 Viscosity	A	The mean viscocity of the product was reported to be 33.7 mm^2/s at 20.0±0.5°C; and 16.6 mm^2/s at	471090-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		40.0±0.5°C (using a capillary viscometer method; specified in Method 114 of the OECD Guidelines for Testing of Chemicals).	
830.7200 Melting Point/Melting Range	NA	Not required for manufacturing-use products.	
830.7220 Boiling Point/Boiling Range	NA	Not required for manufacturing-use products.	
830.7300 Density/Relative Density/Bulk Density	A	The relative density of the product was reported to be 0.964 at 20.0±0.5°C (using the pycnometer method; Method 109 of the OECD Guidelines for Testing of Chemicals).	471090-01
830.7370 Dissociation Constants in Water	NA	Not required for manufacturing-use products.	
830.7550/830.7560/830.7570 Partition Coefficient	NA	Not required for manufacturing-use products.	
830.7840/830.7860 Water Solubility	NA	Not required for manufacturing-use products.	
830.7950 Vapor Pressure	NA	Not required for manufacturing-use products.	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

CONCLUSION:

This amendment , which requested approval for the registration of a new manufacturing product entitled "SilvaDur", is accepted considering all the product chemistry data submitted under MER ID # 471090-01 and the current CSF.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Tuesday, July 31, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 707-GRG/ SilvaDur
DP Barcode: D340171

To: Marshall Swindell, PM 33/ Karen Leavy
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: for Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Rohm & Haas Company

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Silver	2.95
Other Ingredient(s):	97.05
Total:	100.00

1) BACKGROUND: The Rohm & Haas Company has submitted a complete set of six acute toxicity studies. The acute inhalation toxicity study was conducted by WIL Research Laboratories, Limited Liability Company (LLC). The other five studies were conducted by MB Research Laboratories.

While the product is named "Silva Dur", the test material is named "QR-1727". The Chemistry and Toxicology Team (CTT) contacted the registrant who replied via an email (7/13/2007). Part of this email states:

> "QR-1727 is the experimental designation of SilvaDur™. QR-1727 and SilvaDur™ are the same entity."

A primary review of these studies was conducted by the Product Science Branch (PSB)/Antimicrobials Division (AD) contractor, Computer Sciences Corporation (CSC). The Chemistry and Toxicology Team (CTT) conducted a brief secondary review to assure that the studies meet EPA/OPP criteria.

2) RECOMMENDATIONS: PSB findings are:

a) The acute oral toxicity study is acceptable. There was an issue in that the report did not specifically state that the product was administered via gavage. CTT telephoned the test facility. The study director states that the test material was applied via gavage.
b) The acute dermal and acute inhalation toxicity studies are acceptable.
c) The primary eye irritation study is acceptable. The study was terminated early due to the severe ocular effects observed following treatment.
d) The primary skin irritation study is acceptable. This study, and its results, were unusual for the following reasons:
   i) The lab tested the product using 3-minute, 1-hour and 4-hour exposures. Typically, the primary skin irritation study is conducted using a single 4-hour exposure.
   ii) The study used one test animal (with three test sites on that single animal). The lab was able to achieve conclusive results using the 3-minute exposure.
   iii) After the three minute exposure, the testing facility (the lab) reported "**black areas, indicative of injuries in depth**". CTT rarely observes irritation this severe.

   The lab also reported severe erythema, moderate edema and eschar. CTT reports this information in order to impress upon the PM Team the *extreme* irritation caused by SilvaDur in this study.

e) The dermal sensitization study is acceptable. This study was classified as a weak sensitizer, which is the mildest grade possible for this study. As such, CTT is classifying this product a non-sensitizer.

The acute toxicity profile for File Symbol 707-GRG is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	471090-02	III	Acceptable
Acute Dermal Toxicity	471090-03	IV	Acceptable
Acute Inhalation Toxicity	471090-04	IV	Acceptable
Primary Eye Irritation	471090-05	I	Acceptable
Primary Skin Irritation	471090-06	I	Acceptable
Dermal Sensitization	471090-07	Nonsensitizer	Acceptable

3) LABELING:

a) The signal word is "DANGER", based upon the results of the primary eye and skin irritation studies.

b) The Precautionary Statements should state:

"Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical resistant footwear and chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse."

i) The submitted label contains a section above the Precautionary Statements which displays the following statements:

- Corrosive
- Causes irreversible eye damage.
- Causes skin burns.
- Harmful if swallowed.
- Harmful if absorbed through skin.
- Harmful if inhaled.

These statements are acceptable to CTT. The statements "Harmful if absorbed through skin" and "Harmful if inhaled" are not required, based on the results of the submitted studies. However, they are

toxicity category III statements and may be retained if the registrant feels that they will add an additional level of safety.

c) The First Aid statements should state:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing.
- Call a Poison Control Center for treatment advice.

If on Skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center for treatment advice.

If Swallowed:

- Call a Poison Control Center immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

The submitted label contains a First Aid statement for acute inhalation exposure. Based upon the submitted acute inhalation toxicity study, this First Aid statement is not required. However, the registrants may retain this statement if they choose to do so.

d) This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye and skin irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards).

e) Based upon data placing it in toxicity category I for primary eye and skin irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP **in addition to** Restricted-Use Classification. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.

1DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)

Product Manager: 33
MRID No.: 471090-02

Reviewer: CSC and Ian Blackwell
Completion Date: September 21, 2006
Report No.: MB 06-14608.01

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Albert C. Gilotti, Ph.D.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was conducted in accordance with GLP regulations of the EPA 40 CFR 160.

Test Material: QR-1727
Batch #: DR 5324 / Yellow liquid

Dosage: 5,000 and 2,000 mg/kg (administered as received)

Species: 5 Rats; Wistar, albino
Sex: 5 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-11 weeks old)
Weight: 189-227 grams pre-test
Source: Ace Animals, Boyertown, PA
Housing: Temperature Range: 14-24°C
Relative Humidity: 42-86%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

2**Conclusion**:

1. **LD_{50} (mg/kg)**: Female rats: 5,000 > *X* >2,000 mg/kg

2. **Toxicity Category**: III **Classification**: Acceptable

3**Procedure (Deviations from 870.1100)**:

- The report does not state that the product was administered via **gavage**.
- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."
- The guidelines state that the relative humidity should preferably not exceed 70%. The laboratory reported an upper limit of 86% for the relative humidity range.
- The guidelines state that rats should be fasted overnight, prior to dosing. The laboratory withheld food from the rats for 16-20 hours prior to dosing.
- The stopping criteria state that testing should be stopped when 3 consecutive animals survive at the upper bound. The laboratory stopped testing after 4 consecutive animals survived at the upper bound.
- Individual body weights of test animals were recorded; however, changes in body weights were not calculated.

Results:

Reported Mortality

Dosing Sequence	Animal No. / Sex	Dose Level (mg/kg)	Outcome
1	1 / F	5,000	D
2	2 / F	2,000	S
2	3 / F	2,000	S
2	4 / F	2,000	S
2	5 / F	2,000	S

S – Survival; D – Death

Clinical Observations: One animal died by Day 1, following the 5,000 mg/kg oral dose. There were no abnormal physical signs noted prior to death. One survivor lost weight between Day 7 and Day 14. Body weight changes were normal in the other survivors. There were no abnormal physical signs noted in the survivors during the observation period.

Gross Necropsy Findings: Necropsy results for the non-surviving animal revealed red staining of the nose/mouth area, dark areas on the pancreas, lungs paler than normal with red areas, pale areas on the liver, pale and dark areas on the spleen, stomach distended with fluid, and dark areas on the intestines. Necropsy results were normal in the survivors.

4DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

Product Manager: 33
MRID No.: 471090-03

Reviewers: CSC and Ian Blackwell
Completion Date: October 5, 2006
Report No.: MB 06-14522.02

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Albert C. Gilotti, Ph.D.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice compliance was included stating that this study meets the Good Laboratory Practices of the EPA, 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727, Batch #: DR 5314 / Yellow liquid

Dosage: 5,000 mg/kg (administered as received)

Species: 10 Rats; Wistar, albino
Sex: 5 Males and 5 Females. Females were nulliparous and non-pregnant.
Age: Approximately 9-10 weeks old
Weight: Males: 309-366 grams; Females: 200-216 grams; pretest
Source: Ace Animals, Boyertown, PA
Housing: Temperature Range: 19-24°C
Relative Humidity: 33-72%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least one week

Summary:

1. **LD_{50} (mg/kg)**: Male and Female rats: >5,000 mg/kg

2. **The estimated dermal LD_{50} is** greater than 5,000 mg/kg in male and female rats.

3. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from 870.1200):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."
- The guidelines state that the relative humidity should preferably not exceed 70%. The laboratory reported an upper limit of 72% for the relative humidity range.
- The guidelines state that after completion of the study in one sex, at least one group of five animals of the other sex is dosed to establish that animals of this sex are not markedly more sensitive to the test substance. The

laboratory appears to have treated both the male and female animals at the same time.

- The guidelines state that the test substance should be held in contact with the skin with a porous gauze dressing and non-irritating tape throughout the 24-hour exposure period. The laboratory reported that, after application, the test substance was covered with an impervious cuff and plastic-lined elastic bandage and secured with adhesive tape.
- Individual body weights of test animals were recorded; however, changes in body weights were not calculated.

Results:

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Total
5,000	0 / 5	0 / 5	0 / 10

Observations: All ten animals survived the 5,000 mg/kg dermal application. Instances of chromodacryorrhea, chromorhinorrhea, wetness and soiling of the anogenital area, the appearance of dryness in the right eye, and alopecia in the eye area were observed during this study. Dermal effects of erythema, edema, eschar, brown areas, pale areas, flaking skin, shiny areas, and staining of the dose area from the test substance were noted during the study. Three males lost weight between Day 0 and Day 7, but gained weight by Day 14. One female lost weight between Day 7 and Day 14. Body weight changes were normal in the remaining six animals.

Gross Necropsy Findings: Necropsy revealed alopecia on the neck and the eye area and brown staining and eschar of the treated site.

5DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)

(NOSE-ONLY EXPOSURE)

Product Manager: 33
MRID No.: 471090-04

Reviewer: CSC and Ian Blackwell
Completion Date: November 3, 2006
Report No.: WIL-91032

Testing Laboratory: WIL Research Laboratories, LLC, Ashland, OH
Author: Daniel T. Kirkpatrick, Ph.D., D.A.B.T.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was conducted in compliance with U.S. EPA GLP standards (40 CFR Part 160).

Test Material: QR-1727
Batch #: DR 5314 / Translucent, yellow, slightly viscous liquid

Species: 30 Rats; Crl:CD(SD), albino
Sex: 15 Males and 15 Females.
[The laboratory did not report whether females were nulliparous and non-pregnant.]
Age: Young adult (8-10 weeks old)
Source: Charles River Laboratories, Raleigh, NC
Weight: Males: 272-340 grams; Females: 200-249 grams
Housing: Temperature: 69.3-70.9°F (i.e., 20.7-21.6°C)
Humidity: 36.6-52.4%
Photoperiod: 12-hour light/dark cycle
Acclimation: Minimum of 7 days (acclimation to the laboratory)
At least 1 hour (acclimation to restraint in the nose-only tubes)

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	1.9	15.9
II	5.5	40.8
III	7.4	57.9

Summary:

1. **LC_{50} (mg/L) 4-hr exposure**: 6.07 mg/L (95% confidence limit, 4.85 to 7.61 mg/L) in male and female albino rats.

2. **The estimated 4-hr acute inhalation LC_{50} of QR-1727 is 6.07 mg/L (95% confidence limit, 4.85 to 7.61 mg/L) in male and female albino rats.**

3. **Average MMAD**: 1.3±2.78 µm at the 1.9 mg/L exposure level
1.6±2.24 µm at the 5.5 mg/L exposure level
1.8±2.45 µm at the 7.4 mg/L exposure level

4. Toxicity Category: IV **Classification**: Acceptable

Procedure (Deviations from 870.1300):

1) The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
2) The laboratory reported that: "This study was conducted in accordance with the protocol and protocol amendments, except for the following: Protocol Section 7.5 states that airflow rates through the exposure system will be noted in the system description. The system description states that the total airflow rate through the conventional nose-only system will be approximately 20 to 55 L/minute. On 10 August 2006, the airflow rates for the 1.9 mg/L group ranged from 98.1 to 102.3 L/minute during animal exposure. On 24 August 2006, the airflow rates for the 7.4 mg/L group ranged from 50.7 to 61.4 L/minute during animal exposure. Protocol Section 8.1 states that animals will be observed daily for 14 days for pharmacotoxic signs and twice daily (morning and afternoon) for mortality. On 5 September 2006, the afternoon mortality check was inadvertently not performed for the 7.4 mg/L group. These deviations did not negatively impact the quality or integrity of the data, nor the outcome of the study."
3) The guidelines state that if no lethality is demonstrated at a limit test exposure level of 2 mg/L for 4 hours, no further testing for acute inhalation toxicity is needed. The laboratory performed a limit test at an exposure of 1.9 mg/L (target concentration of 2 mg/L) with no mortality observed; however, the laboratory continued the study at higher exposure concentrations.
4) The guidelines state that after completion of the study in one sex, at least one group of five animals of the other sex should be exposed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female groups simultaneously.
5) The guidelines state that, if females are used, they must be nulliparous and non-pregnant. The laboratory did not report whether the female animals were nulliparous and non-pregnant.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number Dead / Number Tested		
	Males	Females	Combined
1.9	0 / 5	0 / 5	0 / 10
5.5	2 / 5	2 / 5	4 / 10
7.4	5 / 5	2 / 5	7 / 10

Chamber Atmosphere

Exp. Conc. (mg/L)	Sample	MMAD (µm)	GSD (µm)	Cumulative % of Particles at Effective Cutoff Diameter (µm)						
				0.26	0.43	0.71	1.18	1.94	3.20	5.27

1.9	1	1.4	2.90	6.2	15.2	25.5	42.9	62.9	76.1	91.2
	2	1.3	2.48	4.3	17.4	28.1	47.3	55.5	74.0	97.1
	3	1.3	2.96	7.1	14.6	27.3	47.4	66.1	77.6	90.1
5.5	1	1.8	2.09	0.0	2.0	12.2	31.9	52.6	71.8	93.4
	2	1.6	2.13	0.7	4.8	16.9	36.7	59.8	79.9	94.6
	3	1.3	2.49	4.6	12.7	24.9	45.4	68.6	80.9	95.3
7.4	1	1.8	2.44	2.3	5.3	13.4	29.3	49.3	69.4	92.0
	2	1.8	2.37	1.7	4.0	13.5	31.7	50.8	69.3	91.7
	3	1.9	2.54	1.5	5.5	15.3	31.1	49.1	67.3	87.0

Chamber Environment During Exposure

Exposure Level (mg/L)	**1.9**	**5.5**	**7.4**
Chamber Volume (L)	8.6	8.6	8.6
Total Airflow (Lpm)	98.1-102.3	38.9-40.1	50.7-61.4
Mean Oxygen Content (%)	20.4	20.4	20.4
Mean Temperature (°C)	20	21	20
Mean Relative Humidity (%)	36	56	61

Clinical Observations: Rales was observed immediately following exposure in all animals in the 1.9 mg/L group; 4 males and 3 females in the 5.5 mg/L group; and 3 females in the 7.4 mg/L group. Labored respiration was observed in some animals treated at all levels of exposure. Tremors, hypoactivity, and gasping were observed in some animals in the 5.5 mg/L and 7.4 mg/L groups, immediately following exposure. There were no other toxicologically significant clinical signs immediately following exposure. Several animals were noted with yellow material on the forelimbs, trunk, rump and urogenital area; clear material around the eyes, mouth, head and facial area; red material around the nose; and/or partial closure of the eyes immediately following exposure. The laboratory noted that these findings are typical for animals restrained in nose-only tubes for 4 hours. However, the portion of the body surface with yellow and clear material may have been greater following test substance exposure than is typically observed following tube restraint for 4 hours. White material around the nose was noted immediately following exposure in the 5.5 and 7.4 mg/L groups, which is attributed to deposition of the test substance via the nose-only route of exposure. No toxicologically significant clinical signs were noted in the 1.9 mg/L group during the 14-day post-exposure observation period. For the 5.5 mg/L and 7.4 mg/L groups, clinical observations included rales, labored respiration, unkempt appearance, gasping, and hypoactivity in some male and female animals during the 14-day observation period. Some female animals in the 5.5 mg/L and 7.4 mg/L groups exhibited thin body, decreased defecation, tremors, and decreased urination. Some male animals in the 5.5 mg/L group exhibited prostration, body cool to touch, and decreased respiration during the 14-day observation period. No male animals in the 7.4 mg/L group survived post-exposure. There were no other toxicologically significant clinical signs during the 14-day post-

exposure observation period and all animals in the 1.9 mg/L group were considered normal by Day 1. Some clinical findings noted in the 5.5 and 7.4 mg/L groups persisted through the duration of the 14-day post exposure observation period.

Body Weights: From Day 0 to 7, one male in the 5.5 mg/L group lost 80 grams, 3 females in the 5.5 mg/L group lost between 4 and 33 grams, and 2 females in the 7.4 mg/L group lost between 8 and 51 grams. Body weight gain during the Day 7 to 14 interval appeared to be higher than during the Day 0 to 7 interval for 5 males and 3 females in the 1.9 mg/L group, 3 males and 2 females in the 5.5 mg/L group, and all surviving females in the 7.4 mg/L group. Therefore, the test substance exposure appeared to produce lower body weight gain during the period immediately following exposure. By Day 14, one male and 1 female in the 5.5 mg/L group were 43 and 42 grams less, respectively, than their initial (Day 0) body weight. All other surviving animals surpassed their initial body weight by Day 14.

Gross Necropsy Findings: For animals that died, lungs were not fully collapsed was the only internal macroscopic finding noted for one male (i.e., 36047) in the 7.4 mg/L group. At the scheduled necropsy, dark red areas on the lungs were noted for one male (i.e., 34388) in the 5.5 mg/L group, gas-filled distended intestine was noted for one male (i.e., 34395) in the 5.5 mg/L group, and dark red areas on the thymus were noted for one male (i.e., 34374) and one female (i.e., 34404) in the 1.9 mg/L group. There were no other gross findings for animals at the scheduled necropsy.

6DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 33
MRID No.: 471090-05

Reviewer: CSC and Ian Blackwell
Completion Date: October 5, 2006
Report No.: MB 06-14522.04

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Daniel R. Cerven, M.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the GLP requirements of EPA 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR 5314 / Yellow liquid

Dosage: 0.1 mL (instilled as received)

Species: 1 Rabbit; New Zealand, white
Sex: Male
Age: Adult (approximately 16 weeks old)
Weight: 3.5 kilograms pretest
Source: Millbrook Breeding Labs, Amherst, MA
Housing: Temperature: 18-22°C
Humidity: 34-74%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Summary:

1. **Toxicity Category**: I

2. **Classification**: Acceptable

Procedure (Deviations from 870.2400):

6) The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
7) The laboratory noted the following protocol deviation: "The terminal body weight of the test animal was not recorded. This deviation did not appear to have an effect on the outcome of the study."
8) The guidelines state that the period of observation should be at least 72 hours. The laboratory terminated the study after 48 hours based on the severe reactions of the test animal.

Results:

Ocular responses in the treated eye were severe through 48 hours, at which time the study was terminated. The control eye appeared normal at each observation period. There were no abnormal physical signs noted during the observation period.

Ocular administration of the test substance produced a corrosive response.

Incidence of Irritation

Time Post Instillation	No. of Animals Testing "Positive" / No. of Animals Tested		
	Corneal Opacity	Iritis	Conjunctivae
1 hour	1 / 1	1 / 1	1 / 1
24 hours	1 / 1	1 / 1	1 / 1
48 hours	1 / 1	1 / 1	1 / 1

Individual Scores for Ocular Irritation

Observations	Rabbit No. G8506 (Male)[1]		
	Hours After Treatment		
	1 hour	24 hours	48 hours
I. Corneal Opacity	3	b	x
II. Iris	1	x	x
III. Conjunctivae			
A. Redness	3	3	3
B. Chemosis	3	4	4
C. Discharge	3a	2	2

[1]vocalization post dose
a – red discharge; b – opacity noted/ unable to determine extent due to chemosis; x – unable to determine score due to the extent of chemosis

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

Product Manager: 33
MRID No.: 471090-06

Reviewers: CSC and Ian Blackwell
Completion Date: October 5, 2006
Report No.: MB 06-14522.03

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Daniel R. Cerven, M.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the GLP requirements of EPA 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR 5314 / Yellow liquid

Dosage: 0.5 mL (applied as received)

Species: 1 Rabbit; New Zealand, white
Sex: Male
Age: Approximately 12 weeks old
Weight: 2.2 kilograms pretest
Source: Millbrook Breeding Labs, Amherst, MA
Housing: Temperature: 18-24°C
Humidity: 19-70%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Summary:

1. **Toxicity Category**: I

2. **Classification**: ___

Procedure (Deviations from 870.2500):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that additional observations were recorded at 72 hours and on Days 7 and 14 for Site #1 and on Days 7 and 14 for Site #2, as an amendment to the protocol, at the request of the Sponsor.
- The laboratory states that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."

Results:
3-Minute Exposure: Erythema was moderate following the 3-minute exposure. **Black areas indicative of injuries in depth were noted.** The black areas were considered a response to the test substance. Edema was very slight following the 3-minute exposure. Additional observations at 72 hours revealed **moderate eschar**

and very slight edema. By Day 7, this site had **severe eschar and well defined edema**. By Day 14, moderate eschar and poor hair re-growth were noted, but there was no edema.

1 Hour Exposure: Erythema and edema were moderate following the 1-hour exposure. By Day 7, erythema was severe and edema was well defined. By Day 14, moderate eschar and poor hair re-growth were noted although there was no edema.

4 Hour Exposure: At 60 minutes following the 4-hour exposure, erythema was severe with pale areas noted. Edema was moderate. At 24 hours and 48 hours, erythema was severe with black areas, indicative of injuries in depth. The black areas were considered a response to the test substance. Edema was well defined. By 72 hours, moderate eschar and well-defined edema were noted. On Day 7, severe eschar was noted with well-defined edema. By Day 14 moderate eschar with pale areas and poor hair re-growth were noted, although there was no edema. There were no abnormal physical signs noted during the observation period.

Body weight changes were normal.

Incidence of Irritation

Time after Patch Removal	No. of Animals Testing "Positive" / No. of Animals Tested	
	Erythema	Edema
60 minutes	1 / 1	1 / 1
24 hours	1 / 1	1 / 1
48 hours	1 / 1	1 / 1
72 hours	1 / 1	1 / 1
7 days	1 / 1	1 / 1
14 days	1 / 1	0 / 0

Individual Skin Irritation Scores

Animal No. G8609 (Male)		Erythema / Edema					
		Time After Patch Removal					
Site #	Exposure Time	60 Mins	24 Hours	48 Hours	72 Hours	7 Days	14 Days
1	3 minutes	3^{b} / 1	NR	NR	>4m / 1	>4s / 2	>4m c / 0
2	1 hour	3 / 3	NR	NR	NR	4 / 2	>4m c / 0
3	4 hours	4^{p} / 3	4^{b*} / 2	4^{b} / 2	>4m / 2	>4s / 2	>4m c p / 0

b – black area (due to test substance); c – poor hair re-growth; p – pale areas; * – re-clipped
>4m – moderate eschar; >4s – severe eschar
NR – score not recorded

DATA REVIEW FOR GUINEA PIG MAXIMIZATION TEST (OPPTS 870.2600)
(MAGNUSSON-KLIGMAN)

Product Manager: 33
MRID No.: 471090-07

Reviewer: CSC and Ian Blackwell
Completion Date: October 5, 2006
Report No.: MB 06-14522.06

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Debra A. Hall, L.A.T.G.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the GLP requirements of the EPA, 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR5314 / Yellow liquid

Positive Control Material: 2-Mercaptobenzothiazole
(Historical data completed on May 15, 2006)

Species: 36 Guinea pigs; Hartley albino
Sex: Range-Finding: 3 Females (intradermal)
1 Male and 2 Females (topical)
Test Group: 10 Males and 10 Females
Control Group: 5 Males and 5 Females
[The laboratory did not report whether females were nulliparous and non-pregnant.]
Age: Approximately 3-4 weeks old
Weight: Males: 267-336 grams; Females: 263-348 grams; pretest
Source: Elm Hill Breeding Labs, Chelmsford, MA
Housing: Temperature Range: 17.22-23.89°C
Relative Humidity: 35-59%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Method: Magnusson-Kligman

Summary:

1. **Based on these findings and on the evaluation system used, QR-1727 is classified as having a weak sensitizing potential.**

2. **Classification**: Acceptable

Procedure (Deviations from 870.2600):

4) The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
5) The laboratory noted that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."
6) The guidelines indicate that young adult guinea pigs are preferred. The laboratory used guinea pigs that were approximately 3-4 weeks old. OPPTS 870.1200 identifies young adult guinea pigs as being between 5-6 weeks old.
7) The guidelines state that, if females are used, they must be nulliparous and non-pregnant. The laboratory did not report whether the female animals were nulliparous and non-pregnant.
8) The laboratory only graded erythema, and not edema, although the guidelines require that as a minimum, the erythema and edema must be graded.

Procedure:

Site Preparation: On the day prior to the screen, Induction A, Induction B, or Challenge, the sites (back or sides) were clipped free of hair with an electric clipper. Upon examination prior to the screen or Induction A, animals with skin irregularities or irritation were eliminated from the study.

Preliminary Screen: The preliminary screen was conducted to determine the concentration for intradermal injection which was not necrotic, ulcerogenic, or toxic. For the topical application, the concentration of the test substance must be well tolerated systemically and produce no more than mild to moderate skin irritation. Based on the results of the preliminary screen, the intradermal concentration selected was 1%, and the topical concentration selected was 50%.

The test substance was prepared in distilled water to the following five concentrations: 1, 5, 10, 25, and 50%. Three guinea pigs were dosed intradermally using a syringe and 23-gauge needle, with 0.1 mL of each of the following test substance concentrations: 1, 5, 10, and 25%. Three other guinea pigs were dosed topically with 0.1 mL of each of the following test substance concentrations: 1, 10, 25, and 50%. For the topical applications, 0.1 mL of the test substance concentration was applied to 2 x 2 cm squares of Whatman's #1 filter paper which were applied to the skin. The patches, occluded with plastic and fastened with non-irritating tape, remained in place for 24 hours.

Based on the results of the intradermal injections, a 1% concentration – a dose which was not necrotic, ulcerogenic, or toxic – was chosen for Induction A. Based on the results of the topical doses, a 50% concentration – a dose which was well tolerated systemically and produced no more than mild to moderate skin irritation – was chosen for Induction B. Based on the results of the topical doses, a 1% concentration – a dose of the highest non-irritating concentration – was chosen for the Challenge. The intradermal sites were scored 24 hours and 3 days after dosing. The topical sites were scored 24 and 48 hours after patch removal. Erythema was evaluated according to a scoring system provided in the laboratory report.

Sensitization Study: There are two stages to the maximization test. The first stage is the induction and consists of intradermal injections followed in 7 days by a topical application of the test substance. The second stage is the challenge which consists

of a topical application performed 14 days following completion of the induction phase. One group of ten guinea pigs per sex served as the test substance group. One group of five guinea pigs per sex served as the control group.

Induction A – Six intradermal injections, using a 23-guage needle, were made on the 4 x 6 cm prepared site. Sites "a" received 0.1 mL of 50% Freunds Complete Adjuvant (FCA) in distilled water. Sites "b" received 0.1 mL of a 1% concentration of the test substance on both sides or 100% distilled water on both sides. Sites "c" received 0.1 mL of a mixture containing equal parts of 50% FCA and a 1% concentration of the test substance on both sides or equal parts of 50% FCA and distilled water on both sides.

Induction B – Seven days after Induction A, the guinea pigs in the test substance group were dosed topically using 2 x 4 cm patches of Whatman's #1 filter paper, saturated with 0.2 mL of the 50% concentration. The patches, occluded with plastic and fastened with adhesive tape, remained in place for 48 hours. The guinea pigs in the control group were dosed in the same manner with the vehicle control.

Challenge Application – Fourteen days after Induction B, the test and control animals were challenged topically using 2 x 2 cm patches of Whatman's #1 filter paper, saturated with 0.1 mL of a 1% dilution of the test substance. The vehicle was applied topically. All sites were occluded with plastic and secured with non-irritating tape for 24 hours.

Challenge Re-Clip – At least 5 hours prior to recording the 24-hour dermal observations, the sites were closely re-clipped.

Results:
Test Substance:
Induction A: Erythema was absent to intense.
Induction B: Erythema was discrete to moderate.
Challenge: Erythema was absent in 19/20 animals on the test substance site. Discrete erythema was noted in 1/20 animals at the 48-hours scoring only. Erythema was absent on the vehicle control site. Based on these results, Magnusson, B. & Kligman, A.M., Journal of Investigative Dermatology, 52, p. 268, 1969, would classify the material as having a weak sensitizing potential.

Vehicle Control: 100% distilled water
Induction A: Erythema was absent to moderate.
Induction B: Erythema was absent to discrete.
Challenge: Erythema was absent on both the test substance site and the vehicle control site.

In Group 1, one male animal had diarrhea and soiling of the anogenital area for three days and one mail had soiling of the anogenital area for one day. In Group 2, wetness of the anogenital area was noted in one male. All other animals appeared normal through the study.

Body weight changes were normal.

Historical Positive Control: The procedures used in this study were validated using 2-Mercaptobenzothiazole 97% as a positive control substance. The study was completed on May 15, 2006. The test was conducted with Hartley albino guinea pigs

from Elm Hill Breeding Labs, Chelmsford, MA. The test was conducted following induction and challenge procedures similar to those described above.

Conclusion:
In the challenge phase, the test substance did not show an incidence of erythema of at least 30%, which is the minimal response required (according to "Official Journal of the European Communities," No. L 110A) to indicate delayed contact hypersensitivity.

Test Animal Group Skin Reaction Scores

Treatment Phase	Post-Induction A Dermal Observations											
	FCA				Test Substance				FCA/ Test Substance			
Concentration	50%				1%				50% / 1%			
Site	Site a Left		Site a Right		Site b Left		Site b Right		Site c Left		Site c Right	
Hours	24 / 48		24 / 48		24 / 48		24 / 48		24 / 48		24 / 48	
Animal No. / Sex												
Test Group												
C10433 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10434 / M	1	1	0	0	2	2	2	2	2p	2p	2p	2p
C10435 / M	1	1	1	1	2	2	2	2	2	2p	2	2
C10436 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10437 / M	1	1	1	1	2	2	2	2	2p	2p	2	2
C10438 / M	1	1	0	0	2	2	0	0	0	0	2	2
C10439 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10440 / M	1	1	1	1	2	2	0	0	2	2	2	2
C10441 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10442 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10443 / F	1	1	1	1	0	0	2	3	2	2	2	2
C10444 / F	1	0	1	1	1	0	1	0	2	2	1	1
C10445 / F	1	1	1	1	2	2	2	2	1	1	1	1
C10446 / F	1	1	1	1	2	2	2	2	1	1	2	2
C10447 / F	1	1	1	1	2	2	2	2	2p	2p	2p	2p
C10448 / F	1	1	0	0	3	3	1	2	1	1	1	1
C10449 / F	1	1	1	1	1	1	2	2	1	0	1	1
C10450 / F	1	1	1	1	0	0	0	0	1	1	0	0
C10451 / F	1	0	1	0	2	2	0	0	1	0	1	1
C10452 / F	1	1	1	1	1	2	2	2	1	1	1	1

p – pale areas

Treatment Phase	Induction B		Challenge			
Concentration	50% Test Substance		1% Test Substance		100% Distilled Water	
Site			Left Flank		Right Flank	
Hours		48	24	48	24 / 48	24 / 48
Animal No. /Sex						
C10433 / M		2	0	0	0	0
C10434 / M		2	0	0	0	0
C10435 / M		1	0	0	0	0
C10436 / M		2	0	0	0	0
C10437 / M		1	0	0	0	0
C10438 / M		2	0	0	0	0
C10439 / M		2	0	0	0	0
C10440 / M		1	0	0	0	0
C10441 / M		1	0	0	0	0
C10442 / M		2	0	1	0	0
C10443 / F		2	0	0	0	0
C10444 / F		2	0	0	0	0
C10445 / F		1	0	0	0	0
C10446 / F		2	0	0	0	0
C10447 / F		1	0	0	0	0
C10448 / F		2	0	0	0	0
C10449 / F		1	0	0	0	0
C10450 / F		2	0	0	0	0
C10451 / F		1	0	0	0	0
C10452 / F		2	0	0	0	0

Inert Ingredient Information may be entitled to confidential treatmernt

Ian Blackwell/DC/USEPA/US
07/11/2007 11:55 AM

To jhagan@rohmhaas.com
cc Michele Wingfield/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
bcc Wallace Powell/DC/USEPA/US@EPA
Subject SilvaDur

To: James V. Hagan
Regulatory Affairs Manager
Rohm and Haas Company

Dear. Mr. Hagan,

I am assigned the review of the acute toxicity studies that you have submitted in support of EPA File Symbol 707-GRG. While your product is named "SilvaDur", the test material used in these studies is "QR-1727". Your cover letter does not seem to discuss this discrepancy.

Your cover letter does mention a material known as [redacted] That product is an inert ingredient. [redacted]

Can you please identify QR-1727 and its relationship to SilvaDur?

Ian Blackwell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

CC: Michele Wingfield, Marshall Swindell

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)

Product Manager: 33
MRID No.: 471090-02

Reviewer: Karen Hicks
Completion Date: September 21, 2006
Report No.: MB 06-14608.01

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Albert C. Gilotti, Ph.D.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was conducted in accordance with GLP regulations of the EPA 40 CFR 160.

Test Material: QR-1727
Batch #: DR 5324 / Yellow liquid

Dosage: 5,000 and 2,000 mg/kg (administered as received)

Species: 5 Rats; Wistar, albino
Sex: 5 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-11 weeks old)
Weight: 189-227 grams pre-test
Source: Ace Animals, Boyertown, PA
Housing: Temperature Range: 14-24°C
Relative Humidity: 42-86%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Conclusion:

1. **LD_{50} (mg/kg)**: Female rats: >2,000 mg/kg

2. **Toxicity Category**: III **Classification**: ___

Procedure (Deviations from 870.1100):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."
- The guidelines state that the relative humidity should preferably not exceed 70%. The laboratory reported an upper limit of 86% for the relative humidity range.
- The guidelines state that rats should be fasted overnight, prior to dosing. The laboratory withheld food from the rats for 16-20 hours prior to dosing.

- The stopping criteria state that testing should be stopped when 3 consecutive animals survive at the upper bound. The laboratory stopped testing after 4 consecutive animals survived at the upper bound.
- Individual body weights of test animals were recorded; however, changes in body weights were not calculated.

Results:

Reported Mortality

Dosing Sequence	Animal No. / Sex	Dose Level (mg/kg)	Outcome
1	1 / F	5,000	D
2	2 / F	2,000	S
2	3 / F	2,000	S
2	4 / F	2,000	S
2	5 / F	2,000	S

S – Survival; D – Death

Clinical Observations: One animal died by Day 1, following the 5,000 mg/kg oral dose. There were no abnormal physical signs noted prior to death. One survivor lost weight between Day 7 and Day 14. Body weight changes were normal in the other survivors. There were no abnormal physical signs noted in the survivors during the observation period.

Gross Necropsy Findings: Necropsy results for the non-surviving animal revealed red staining of the nose/mouth area, dark areas on the pancreas, lungs paler than normal with red areas, pale areas on the liver, pale and dark areas on the spleen, stomach distended with fluid, and dark areas on the intestines. Necropsy results were normal in the survivors.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

Product Manager: 33
MRID No.: 471090-03

Reviewer: Karen Hicks
Completion Date: October 5, 2006
Report No.: MB 06-14522.02

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Albert C. Gilotti, Ph.D.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice compliance was included stating that this study meets the Good Laboratory Practices of the EPA, 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR 5314 / Yellow liquid

Dosage: 5,000 mg/kg (administered as received)

Species: 10 Rats; Wistar, albino
Sex: 5 Males and 5 Females. Females were nulliparous and non-pregnant.
Age: Approximately 9-10 weeks old
Weight: Males: 309-366 grams; Females: 200-216 grams; pretest
Source: Ace Animals, Boyertown, PA
Housing: Temperature Range: 19-24°C
Relative Humidity: 33-72%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least one week

Summary:

1. **LD_{50} (mg/kg)**: Male and Female rats: >5,000 mg/kg

2. **The estimated dermal LD_{50} is** greater than 5,000 mg/kg in male and female rats.

3. **Toxicity Category**: IV **Classification**: ___

Procedure (Deviations from 870.1200):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."
- The guidelines state that the relative humidity should preferably not exceed 70%. The laboratory reported an upper limit of 72% for the relative humidity range.

- The guidelines state that after completion of the study in one sex, at least one group of five animals of the other sex is dosed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female animals at the same time.
- The guidelines state that the test substance should be held in contact with the skin with a porous gauze dressing and non-irritating tape throughout the 24-hour exposure period. The laboratory reported that, after application, the test substance was covered with an impervious cuff and plastic-lined elastic bandage and secured with adhesive tape.
- Individual body weights of test animals were recorded; however, changes in body weights were not calculated.

Results:

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Total
5,000	0 / 5	0 / 5	0 / 10

Observations: All ten animals survived the 5,000 mg/kg dermal application. Instances of chromodacryorrhea, chromorhinorrhea, wetness and soiling of the anogenital area, the appearance of dryness in the right eye, and alopecia in the eye area were observed during this study. Dermal effects of erythema, edema, eschar, brown areas, pale areas, flaking skin, shiny areas, and staining of the dose area from the test substance were noted during the study. Three males lost weight between Day 0 and Day 7, but gained weight by Day 14. One female lost weight between Day 7 and Day 14. Body weight changes were normal in the remaining six animals.

Gross Necropsy Findings: Necropsy revealed alopecia on the neck and the eye area and brown staining and eschar of the treated site.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)
(NOSE-ONLY EXPOSURE)

Product Manager: 33
MRID No.: 471090-04

Reviewer: Karen Hicks
Completion Date: November 3, 2006
Report No.: WIL-91032

Testing Laboratory: WIL Research Laboratories, LLC, Ashland, OH
Author: Daniel T. Kirkpatrick, Ph.D., D.A.B.T.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was conducted in compliance with U.S. EPA GLP standards (40 CFR Part 160).

Test Material: QR-1727
Batch #: DR 5314 / Translucent, yellow, slightly viscous liquid

Species: 30 Rats; Crl:CD(SD), albino
Sex: 15 Males and 15 Females.
[The laboratory did not report whether females were nulliparous and non-pregnant.]
Age: Young adult (8-10 weeks old)
Source: Charles River Laboratories, Raleigh, NC
Weight: Males: 272-340 grams; Females: 200-249 grams
Housing: Temperature: 69.3-70.9°F (i.e., 20.7-21.6°C)
Humidity: 36.6-52.4%
Photoperiod: 12-hour light/dark cycle
Acclimation: Minimum of 7 days (acclimation to the laboratory)
At least 1 hour (acclimation to restraint in the nose-only tubes)

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	1.9	15.9
II	5.5	40.8
III	7.4	57.9

Summary:

1. **LC_{50} (mg/L) 4-hr exposure**: 6.07 mg/L (95% confidence limit, 4.85 to 7.61 mg/L) in male and female albino rats.

2. **The estimated 4-hr acute inhalation LC_{50} of QR-1727 is 6.07 mg/L (95% confidence limit, 4.85 to 7.61 mg/L) in male and female albino rats.**

3. **Average MMAD:** 1.3±2.78 µm at the 1.9 mg/L exposure level
1.6±2.24 µm at the 5.5 mg/L exposure level
1.8±2.45 µm at the 7.4 mg/L exposure level

4. **Toxicity Category:** IV **Classification:** ___

Procedure (Deviations from 870.1300):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory reported that: "This study was conducted in accordance with the protocol and protocol amendments, except for the following: Protocol Section 7.5 states that airflow rates through the exposure system will be noted in the system description. The system description states that the total airflow rate through the conventional nose-only system will be approximately 20 to 55 L/minute. On 10 August 2006, the airflow rates for the 1.9 mg/L group ranged from 98.1 to 102.3 L/minute during animal exposure. On 24 August 2006, the airflow rates for the 7.4 mg/L group ranged from 50.7 to 61.4 L/minute during animal exposure. Protocol Section 8.1 states that animals will be observed daily for 14 days for pharmacotoxic signs and twice daily (morning and afternoon) for mortality. On 5 September 2006, the afternoon mortality check was inadvertently not performed for the 7.4 mg/L group. These deviations did not negatively impact the quality or integrity of the data, nor the outcome of the study."
- The guidelines state that if no lethality is demonstrated at a limit test exposure level of 2 mg/L for 4 hours, no further testing for acute inhalation toxicity is needed. The laboratory performed a limit test at an exposure of 1.9 mg/L (target concentration of 2 mg/L) with no mortality observed; however, the laboratory continued the study at higher exposure concentrations.
- The guidelines state that after completion of the study in one sex, at least one group of five animals of the other sex should be exposed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female groups simultaneously.
- The guidelines state that, if females are used, they must be nulliparous and non-pregnant. The laboratory did not report whether the female animals were nulliparous and non-pregnant.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number Dead / Number Tested		
	Males	Females	Combined
1.9	0 / 5	0 / 5	0 / 10
5.5	2 / 5	2 / 5	4 / 10
7.4	5 / 5	2 / 5	7 / 10

Chamber Atmosphere

Exp. Conc. (mg/L)	Sample	MMAD (µm)	GSD (µm)	Cumulative % of Particles at Effective Cutoff Diameter (µm)						
				0.26	0.43	0.71	1.18	1.94	3.20	5.27
1.9	1	1.4	2.90	6.2	15.2	25.5	42.9	62.9	76.1	91.2
	2	1.3	2.48	4.3	17.4	28.1	47.3	55.5	74.0	97.1
	3	1.3	2.96	7.1	14.6	27.3	47.4	66.1	77.6	90.1
5.5	1	1.8	2.09	0.0	2.0	12.2	31.9	52.6	71.8	93.4
	2	1.6	2.13	0.7	4.8	16.9	36.7	59.8	79.9	94.6
	3	1.3	2.49	4.6	12.7	24.9	45.4	68.6	80.9	95.3
7.4	1	1.8	2.44	2.3	5.3	13.4	29.3	49.3	69.4	92.0
	2	1.8	2.37	1.7	4.0	13.5	31.7	50.8	69.3	91.7
	3	1.9	2.54	1.5	5.5	15.3	31.1	49.1	67.3	87.0

Chamber Environment During Exposure

Exposure Level (mg/L)	1.9	5.5	7.4
Chamber Volume (L)	8.6	8.6	8.6
Total Airflow (Lpm)	98.1-102.3	38.9-40.1	50.7-61.4
Mean Oxygen Content (%)	20.4	20.4	20.4
Mean Temperature (°C)	20	21	20
Mean Relative Humidity (%)	36	56	61

Clinical Observations: Rales was observed immediately following exposure in all animals in the 1.9 mg/L group; 4 males and 3 females in the 5.5 mg/L group; and 3 females in the 7.4 mg/L group. Labored respiration was observed in some animals treated at all levels of exposure. Tremors, hypoactivity, and gasping were observed in some animals in the 5.5 mg/L and 7.4 mg/L groups, immediately following exposure. There were no other toxicologically significant clinical signs immediately following exposure. Several animals were noted with yellow material on the forelimbs, trunk, rump and urogenital area; clear material around the eyes, mouth, head and facial area; red material around the nose; and/or partial closure of the eyes immediately following exposure. The laboratory noted that these findings are typical for animals restrained in nose-only tubes for 4 hours. However, the portion of the body surface with yellow and clear material may have been greater following test substance exposure than is typically observed following tube restraint for 4 hours. White material around the nose was noted immediately following exposure in the 5.5 and 7.4 mg/L groups, which is attributed to deposition of the test substance via the nose-only route of exposure. No toxicologically significant clinical signs were noted in the 1.9 mg/L group during the 14-day post-exposure observation period. For the 5.5

mg/L and 7.4 mg/L groups, clinical observations included rales, labored respiration, unkempt appearance, gasping, and hypoactivity in some male and female animals during the 14-day observation period. Some female animals in the 5.5 mg/L and 7.4 mg/L groups exhibited thin body, decreased defecation, tremors, and decreased urination. Some male animals in the 5.5 mg/L group exhibited prostration, body cool to touch, and decreased respiration during the 14-day observation period. No male animals in the 7.4 mg/L group survived post-exposure. There were no other toxicologically significant clinical signs during the 14-day post-exposure observation period and all animals in the 1.9 mg/L group were considered normal by Day 1. Some clinical findings noted in the 5.5 and 7.4 mg/L groups persisted through the duration of the 14-day post exposure observation period.

Body Weights: From Day 0 to 7, one male in the 5.5 mg/L group lost 80 grams, 3 females in the 5.5 mg/L group lost between 4 and 33 grams, and 2 females in the 7.4 mg/L group lost between 8 and 51 grams. Body weight gain during the Day 7 to 14 interval appeared to be higher than during the Day 0 to 7 interval for 5 males and 3 females in the 1.9 mg/L group, 3 males and 2 females in the 5.5 mg/L group, and all surviving females in the 7.4 mg/L group. Therefore, the test substance exposure appeared to produce lower body weight gain during the period immediately following exposure. By Day 14, one male and 1 female in the 5.5 mg/L group were 43 and 42 grams less, respectively, than their initial (Day 0) body weight. All other surviving animals surpassed their initial body weight by Day 14.

Gross Necropsy Findings: For animals that died, lungs were not fully collapsed was the only internal macroscopic finding noted for one male (i.e., 36047) in the 7.4 mg/L group. At the scheduled necropsy, dark red areas on the lungs were noted for one male (i.e., 34388) in the 5.5 mg/L group, gas-filled distended intestine was noted for one male (i.e., 34395) in the 5.5 mg/L group, and dark red areas on the thymus were noted for one male (i.e., 34374) and one female (i.e., 34404) in the 1.9 mg/L group. There were no other gross findings for animals at the scheduled necropsy.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 33
MRID No.: 471090-05

Reviewer: Karen Hicks
Completion Date: October 5, 2006
Report No.: MB 06-14522.04

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Daniel R. Cerven, M.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the GLP requirements of EPA 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR 5314 / Yellow liquid

Dosage: 0.1 mL (instilled as received)

Species: 1 Rabbit; New Zealand, white
Sex: Male
Age: Adult (approximately 16 weeks old)
Weight: 3.5 kilograms pretest
Source: Millbrook Breeding Labs, Amherst, MA
Housing: Temperature: 18-22°C
Humidity: 34-74%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Summary:

1. **Toxicity Category**: I

2. **Classification**: ___

Procedure (Deviations from 870.2400):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted the following protocol deviation: "The terminal body weight of the test animal was not recorded. This deviation did not appear to have an effect on the outcome of the study."
- The guidelines state that the period of observation should be at least 72 hours. The laboratory terminated the study after 48 hours based on the severe reactions of the test animal.

Results:
Ocular responses in the treated eye were severe through 48 hours, at which time the study was terminated. The control eye appeared normal at each observation period. There were no abnormal physical signs noted during the observation period.

Ocular administration of the test substance produced a corrosive response.

Incidence of Irritation

Time Post Instillation	No. of Animals Testing "Positive" / No. of Animals Tested		
	Corneal Opacity	Iritis	Conjunctivae
1 hour	1 / 1	1 / 1	1 / 1
24 hours	1 / 1	1 / 1	1 / 1
48 hours	1 / 1	1 / 1	1 / 1

Individual Scores for Ocular Irritation

Observations	Rabbit No. G8506 (Male)[1]		
	Hours After Treatment		
	1 hour	24 hours	48 hours
I. Corneal Opacity	3	b	x
II. Iris	1	x	x
III. Conjunctivae			
A. Redness	3	3	3
B. Chemosis	3	4	4
C. Discharge	3a	2	2

[1]vocalization post dose
a – red discharge; b – opacity noted/ unable to determine extent due to chemosis; x – unable to determine score due to the extent of chemosis

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

Product Manager: 33
MRID No.: 471090-06

Reviewer: Karen Hicks
Completion Date: October 5, 2006
Report No.: MB 06-14522.03

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Daniel R. Cerven, M.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the GLP requirements of EPA 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR 5314 / Yellow liquid

Dosage: 0.5 mL (applied as received)

Species: 1 Rabbit; New Zealand, white
Sex: Male
Age: Approximately 12 weeks old
Weight: 2.2 kilograms pretest
Source: Millbrook Breeding Labs, Amherst, MA
Housing: Temperature: 18-24°C
Humidity: 19-70%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Summary:

1. **Toxicity Category**: I

2. **Classification**: ___

Procedure (Deviations from 870.2500):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that additional observations were recorded at 72 hours and on Days 7 and 14 for Site #1 and on Days 7 and 14 for Site #2, as an amendment to the protocol, at the request of the Sponsor.
- The laboratory states that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."

Results:
3-Minute Exposure: Erythema was moderate following the 3-minute exposure. Black areas indicative of injuries in depth were noted. The black areas were considered a response to the test substance. Edema was very slight following the 3-minute exposure. Additional observations at 72 hours revealed moderate eschar and very slight edema. By Day 7, this site had severe eschar and well defined edema. By Day 14, moderate eschar and poor hair re-growth were noted, but there was no edema.

1 Hour Exposure: Erythema and edema were moderate following the 1-hour exposure. By Day 7, erythema was severe and edema was well defined. By Day 14, moderate eschar and poor hair re-growth were noted although there was no edema.

4 Hour Exposure: At 60 minutes following the 4-hour exposure, erythema was severe with pale areas noted. Edema was moderate. At 24 hours and 48 hours, erythema was severe with black areas, indicative of injuries in depth. The black areas were considered a response to the test substance. Edema was well defined. By 72 hours, moderate eschar and well-defined edema were noted. On Day 7, severe eschar was noted with well-defined edema. By Day 14 moderate eschar with pale areas and poor hair re-growth were noted, although there was no edema. There were no abnormal physical signs noted during the observation period.

Body weight changes were normal.

Incidence of Irritation

Time after Patch Removal	No. of Animals Testing "Positive" / No. of Animals Tested	
	Erythema	Edema
60 minutes	1 / 1	1 / 1
24 hours	1 / 1	1 / 1
48 hours	1 / 1	1 / 1
72 hours	1 / 1	1 / 1
7 days	1 / 1	1 / 1
14 days	1 / 1	0 / 0

Individual Skin Irritation Scores

Animal No. G8609 (Male)		Erythema / Edema Time After Patch Removal					
Site #	Exposure Time	60 Mins	24 Hours	48 Hours	72 Hours	7 Days	14 Days
1	3 minutes	3^{b} / 1	NR	NR	>4m / 1	>4s / 2	>4m c / 0
2	1 hour	3 / 3	NR	NR	NR	4 / 2	>4m c / 0
3	4 hours	4^{p} / 3	4^{b*} / 2	4^{b} / 2	>4m / 2	>4s / 2	>4m c p / 0

b – black area (due to test substance); c – poor hair re-growth; p – pale areas; * – re-clipped
>4m – moderate eschar; >4s – severe eschar
NR – score not recorded

DATA REVIEW FOR GUINEA PIG MAXIMIZATION TEST (OPPTS 870.2600)
(MAGNUSSON-KLIGMAN)

Product Manager: 33
MRID No.: 471090-07

Reviewer: Karen Hicks
Completion Date: October 5, 2006
Report No.: MB 06-14522.06

Testing Laboratory: MB Research Laboratories, Spinnerstown, PA
Author: Debra A. Hall, L.A.T.G.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the GLP requirements of the EPA, 40 CFR 160, with the following exception: "Prior to study initiation, the study director was not supplied with the test article characterization information; however, the information was received during the course of the study."

Test Material: QR-1727
Batch #: DR5314 / Yellow liquid

Positive Control Material: 2-Mercaptobenzothiazole
(Historical data completed on May 15, 2006)

Species:	36 Guinea pigs; Hartley albino	
Sex:	Range-Finding:	3 Females (intradermal) 1 Male and 2 Females (topical)
	Test Group:	10 Males and 10 Females
	Control Group:	5 Males and 5 Females
	[The laboratory did not report whether females were nulliparous and non-pregnant.]	
Age:	Approximately 3-4 weeks old	
Weight:	Males: 267-336 grams; Females: 263-348 grams; pretest	
Source:	Elm Hill Breeding Labs, Chelmsford, MA	
Housing:	Temperature Range:	17.22-23.89°C
	Relative Humidity:	35-59%
	Photoperiod:	12-hour light/dark cycle
Acclimation:	At least 5 days	

Method: Magnusson-Kligman

Summary:

1. **Based on these findings and on the evaluation system used, QR-1727 is classified as having a weak sensitizing potential.**

2. **Classification**: ___

Procedure (Deviations from 870.2600):

- The study was conducted using the product, QR-1727. According to the Certificate of Analysis, QR-1727 contains 3.0% silver. The product, SilvaDur, is the product for which registration is being sought. SilvaDur contains 2.95% silver as the active ingredient.
- The laboratory noted that "although the temperature was outside of the protocol-specified range, this minor deviation was not considered to have had any adverse effect on the conduct or results of this study."
- The guidelines indicate that young adult guinea pigs are preferred. The laboratory used guinea pigs that were approximately 3-4 weeks old. OPPTS 870.1200 identifies young adult guinea pigs as being between 5-6 weeks old.
- The guidelines state that, if females are used, they must be nulliparous and non-pregnant. The laboratory did not report whether the female animals were nulliparous and non-pregnant.
- The laboratory only graded erythema, and not edema, although the guidelines require that as a minimum, the erythema and edema must be graded.

Procedure:

Site Preparation: On the day prior to the screen, Induction A, Induction B, or Challenge, the sites (back or sides) were clipped free of hair with an electric clipper. Upon examination prior to the screen or Induction A, animals with skin irregularities or irritation were eliminated from the study.

Preliminary Screen: The preliminary screen was conducted to determine the concentration for intradermal injection which was not necrotic, ulcerogenic, or toxic. For the topical application, the concentration of the test substance must be well tolerated systemically and produce no more than mild to moderate skin irritation. Based on the results of the preliminary screen, the intradermal concentration selected was 1%, and the topical concentration selected was 50%.

The test substance was prepared in distilled water to the following five concentrations: 1, 5, 10, 25, and 50%. Three guinea pigs were dosed intradermally using a syringe and 23-gauge needle, with 0.1 mL of each of the following test substance concentrations: 1, 5, 10, and 25%. Three other guinea pigs were dosed topically with 0.1 mL of each of the following test substance concentrations: 1, 10, 25, and 50%. For the topical applications, 0.1 mL of the test substance concentration was applied to 2 x 2 cm squares of Whatman's #1 filter paper which were applied to the skin. The patches, occluded with plastic and fastened with non-irritating tape, remained in place for 24 hours.

Based on the results of the intradermal injections, a 1% concentration – a dose which was not necrotic, ulcerogenic, or toxic – was chosen for Induction A. Based on the results of the topical doses, a 50% concentration – a dose which was well tolerated systemically and produced no more than mild to moderate skin irritation – was chosen for Induction B. Based on the results of the topical doses, a 1% concentration – a dose of the highest non-irritating concentration – was chosen for the Challenge. The intradermal sites were scored 24 hours and 3 days after dosing. The topical sites were scored 24 and 48 hours after patch removal. Erythema was evaluated according to a scoring system provided in the laboratory report.

Sensitization Study: There are two stages to the maximization test. The first stage is the induction and consists of intradermal injections followed in 7 days by a topical application of the test substance. The second stage is the challenge which consists of a topical application performed 14 days following completion of the induction phase. One group of ten guinea pigs per sex served as the test substance group. One group of five guinea pigs per sex served as the control group.

Induction A – Six intradermal injections, using a 23-guage needle, were made on the 4 x 6 cm prepared site. Sites "a" received 0.1 mL of 50% Freunds Complete Adjuvant (FCA) in distilled water. Sites "b" received 0.1 mL of a 1% concentration of the test substance on both sides or 100% distilled water on both sides. Sites "c" received 0.1 mL of a mixture containing equal parts of 50% FCA and a 1% concentration of the test substance on both sides or equal parts of 50% FCA and distilled water on both sides.

Induction B – Seven days after Induction A, the guinea pigs in the test substance group were dosed topically using 2 x 4 cm patches of Whatman's #1 filter paper, saturated with 0.2 mL of the 50% concentration. The patches, occluded with plastic and fastened with adhesive tape, remained in place for 48 hours. The guinea pigs in the control group were dosed in the same manner with the vehicle control.

Challenge Application – Fourteen days after Induction B, the test and control animals were challenged topically using 2 x 2 cm patches of Whatman's #1 filter paper, saturated with 0.1 mL of a 1% dilution of the test substance. The vehicle was applied topically. All sites were occluded with plastic and secured with non-irritating tape for 24 hours.

Challenge Re-Clip – At least 5 hours prior to recording the 24-hour dermal observations, the sites were closely re-clipped.

Results:
Test Substance:
Induction A: Erythema was absent to intense.
Induction B: Erythema was discrete to moderate.
Challenge: Erythema was absent in 19/20 animals on the test substance site. Discrete erythema was noted in 1/20 animals at the 48-hours scoring only. Erythema was absent on the vehicle control site. Based on these results, Magnusson, B. & Kligman, A.M., Journal of Investigative Dermatology, 52, p. 268, 1969, would classify the material as having a weak sensitizing potential.

Vehicle Control: 100% distilled water
Induction A: Erythema was absent to moderate.
Induction B: Erythema was absent to discrete.
Challenge: Erythema was absent on both the test substance site and the vehicle control site.

In Group 1, one male animal had diarrhea and soiling of the anogenital area for three days and one mail had soiling of the anogenital area for one day. In Group 2, wetness of the anogenital area was noted in one male. All other animals appeared normal through the study.

Body weight changes were normal.

Historical Positive Control: The procedures used in this study were validated using 2-Mercaptobenzothiazole 97% as a positive control substance. The study was completed on May 15, 2006. The test was conducted with Hartley albino guinea pigs from Elm Hill Breeding Labs, Chelmsford, MA. The test was conducted following induction and challenge procedures similar to those described above.

Conclusion:
In the challenge phase, the test substance did not show an incidence of erythema of at least 30%, which is the minimal response required (according to "Official Journal of the European Communities," No. L 110A) to indicate delayed contact hypersensitivity.

Test Animal Group Skin Reaction Scores

Treatment Phase	Post-Induction A Dermal Observations											
	FCA				Test Substance				FCA/ Test Substance			
Concentration	50%				1%				50% / 1%			
Site	Site a Left		Site a Right		Site b Left		Site b Right		Site c Left		Site c Right	
Hours	24 / 48		24 / 48		24 / 48		24 / 48		24 / 48		24 / 48	
Animal No. / Sex												
Test Group												
C10433 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10434 / M	1	1	0	0	2	2	2	2	2p	2p	2p	2p
C10435 / M	1	1	1	1	2	2	2	2	2	2p	2	2
C10436 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10437 / M	1	1	1	1	2	2	2	2	2p	2p	2	2
C10438 / M	1	1	0	0	2	2	0	0	0	0	2	2
C10439 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10440 / M	1	1	1	1	2	2	0	0	2	2	2	2
C10441 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10442 / M	1	1	1	1	2	2	2	2	2	2	2	2
C10443 / F	1	1	1	1	0	0	2	3	2	2	2	2
C10444 / F	1	0	1	1	1	0	1	0	2	2	1	1
C10445 / F	1	1	1	1	2	2	2	2	1	1	1	1
C10446 / F	1	1	1	1	2	2	2	2	1	1	2	2
C10447 / F	1	1	1	1	2	2	2	2	2p	2p	2p	2p
C10448 / F	1	1	0	0	3	3	1	2	1	1	1	1
C10449 / F	1	1	1	1	1	1	2	2	1	0	1	1
C10450 / F	1	1	1	1	0	0	0	0	1	1	0	0
C10451 / F	1	0	1	0	2	2	0	0	1	0	1	1
C10452 / F	1	1	1	1	1	2	2	2	1	1	1	1

p – pale areas

Treatment Phase	Induction B		Challenge			
Concentration	50% Test Substance		1% Test Substance		100% Distilled Water	
Site			Left Flank		Right Flank	
Hours		48	24	48	24 / 48	24 / 48
Animal No. / Sex						
C10433 / M		2	0	0	0	0
C10434 / M		2	0	0	0	0
C10435 / M		1	0	0	0	0
C10436 / M		2	0	0	0	0
C10437 / M		1	0	0	0	0
C10438 / M		2	0	0	0	0
C10439 / M		2	0	0	0	0
C10440 / M		1	0	0	0	0
C10441 / M		1	0	0	0	0
C10442 / M		2	0	1	0	0
C10443 / F		2	0	0	0	0
C10444 / F		2	0	0	0	0
C10445 / F		1	0	0	0	0
C10446 / F		2	0	0	0	0
C10447 / F		1	0	0	0	0
C10448 / F		2	0	0	0	0
C10449 / F		1	0	0	0	0
C10450 / F		2	0	0	0	0
C10451 / F		1	0	0	0	0
C10452 / F		2	0	0	0	0

Inert Ingredient Information may be subject to confidential treatment

James V Hagan
<JHagan@rohmhaas.com>
07/13/2007 08:11 AM

To Ian Blackwell/DC/USEPA/US@EPA
cc Marshall Swindell/DC/USEPA/US@EPA, Michele Wingfield/DC/USEPA/US@EPA
bcc
Subject Re: SilvaDur (EPA File Symbol 707-GRG) - SilvaDur = QR-1727

History: This message has been replied to.

Dear Mr. Blackwell,

Sorry for the confusion we may have caused. Hopefully the following a clear guide to the names designations used in the 707-GRG submission.

SilvaDur™ is the brand name for the antimicrobial product you are reviewing as a
part of the 707-GRG submission.

QR-1727 is the experimental designation of SilvaDur™. QR-1727 and SilvaDur™ are
the same entity.

[redacted] that functions as an inert
ingredient in the SilvaDur™ product. This inert is identified on the CSF for 707-GRG. This inert ingredient has been submitted to the Inert Ingredient Assessment Branch of EPA.

If you have any more questions, please do not hesitate to contact me.

Regards,
Jim

(Embedded image moved to file: pic20663.jpg)

	blackwell.ian@epamail.epa.gov	
To	07/11/2007 11:55 AM	jhagan@rohmhaas.com
cc		Wingfield.Michele@epamail.epa.gov, Swindell.Marshall@epamail.epa.gov
Subject		SilvaDur

To: James V. Hagan
Regulatory Affairs Manager
Rohm and Haas Company

Dear. Mr. Hagan,

I am assigned the review of the acute toxicity studies that you have submitted in support of EPA File Symbol 707-GRG. While your product is named "SilvaDur", the test material used in these studies is "QR-1727". Your cover letter does not seem to discuss this discrepancy.

Your cover letter does mention a material known as [redacted] That product is an inert ingredient. [redacted]

Can you please identify QR-1727 and its relationship to SilvaDur?

Ian Blackwell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

CC: Michele Wingfield, Marshall Swindell


pic20663.jpg

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19016-2399	707-GRG
Active Ingredient(s) and/or representative test compound(s) Silver TGAI	Date 23 August 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Material Preservative and Hard Surface Disinfectant	Product Name SILVADUR(TM) SANITIZER

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☑ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

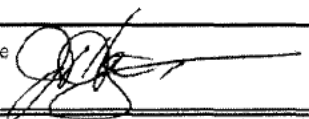
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	23 Aug 2007	James V. Hagan, Regulatory Affairs Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Rohm and Haas Co., 100 Independence Mall West, Philadelphia, PA 19106-2399	EPA Registration Number/File Symbol 707-
Active Ingredient(s) and/or representative test compound(s) silver (Ag+1)	Date April 3, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Materials Preservative and Hard Surface Disinfectant	Product Name SILVADUR(TM) SANITIZER

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of any product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date 4/3/2007	Typed or Printed Name and Title James V. Hagan, Regulatory Affairs Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 4/3/2007	EPA Reg No./File Symbol 707-	Page 1 of 1
Applicant's/Registrant's Name & Address Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106	Product SILVADUR(TM)	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830 Series Group A & B	Product Chemistry		Rohm and Haas Company	Own	GLP-2006-126
870.1100	Acute Oral Toxicity		Rohm and Haas Company	Own	06RC-103
870.1200	Acute Dermal Toxicity		Rohm and Haas Company	Own	06RC-115
870.1300	Acute Inhalation Toxicity		Rohm and Haas Company	Own	06RC-118
870.2400	Primary Eye Irritation		Rohm and Haas Company	Own	06RC-117
870.2500	Primary Dermal Irritation		Rohm and Haas Company	Own	06RC-116
870.2600	Dermal Sensitization		Rohm and Haas Company	Own	06RC-119
	GENERIC DATA REQUIREMENTS	CITE-ALL			

Signature	Name and Title	Date
	James V. Hagar, Regulatory Affairs Manager	04/03/2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

ROHM AND HAAS COMPANY
SPRING HOUSE TECHNICAL CENTER, 727 ARISTOWN ROAD, P.O. BOX 904, SPRING HOUSE, PA 19477-0904 USA
TELEPHONE: (215) 641-7000 FAX: (215) 619-1654

ROHM AND HAAS

April 9, 2007

Document Processing Desk (REGFEE)
Attn: Mr. Marshall Swindell
Antimicrobial Division
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
1200 Pennsylvania Ave. N.W.
Washington, DC 20460-0001

Subject: Application for New End Use Product SilvaDur™

Dear Mr. Swindell,

Please find enclosed applications for registration of the Rohm and Haas Company product SilvaDur™ which contains 2.95% of the active ingredient silver (Ag^{+1}).

SilvaDur™ is a new Antimicrobial End Use Product registration with product chemistry and toxicological studies. Under PRIA we believe this is an A54 EPA Number with product chemistry and toxicological studies. The PRIA fee is $4,200 with a 3 month decision timeline.

The attached Confidential Statements of Formula list the charges for the active ingredient and inert ingredients as charged on a per 100 pound basis. In addition to the raw material charges, the CSF also lists [redacted] found in the inert ingredient [redacted]

The [redacted] in the inert ingredient [redacted] is currently not listed on the TSCA inventory, however we have determined that this [redacted] Additionally on April 2, 2007 we submitted to the inerts branch a request to have [redacted] reviewed and approved as an inert.

This application includes the following enclosed documents for each product:

- Application Form (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Three (3) signed original Basic Confidential Statement of Formula (EPA Form 8570-4)
- Transmittal Document
- Data Matrix Table (EPA Form 8570-35)
- Three (3) copies of each new study identified on the data matrix
- Five (5) copies of the product label

Inert Ingredient Information may be subject to confidential tretament

Please call me at (215) 641-7675 if you have any questions regarding this submission.

Sincerely,

James V. Hagan
Regulatory Affairs Manager
Rohm and Haas Company
Phone 215.641.7675
FAX 215.619.1654
jhagan@rohmhaas.com

Enclosures

ROHM AND HAAS

ROHM AND HAAS COMPANY
SPRING HOUSE TECHNICAL CENTER, 727 NORRISTOWN ROAD, P.O. BOX 904, SPRING HOUSE, PA 19477-0904 USA
TELEPHONE: (215) 641-7000 FAX: (215) 619-1654

ROHM AND HAAS

TRANSMITTAL DOCUMENT

April 9, 2007

Mr. Marshall Swindell (PM33)
Antimicrobial Division
Office of Pesticide Programs (7404C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

SUBJECT: Submission of Various Studies to Support the Registration of SilvaDur™

Dear Mr. Swindell:

Enclosed please find three (3) copies of the following seven (7) studies which Rohm and Haas Company is submitting to the Agency to support the application for the registration of SilvaDur™.

OPPTS Guideline Ref. Number	Study Title
830 Series Group A&B	El A'mma, Beverly J. (2006), QR-1727: Product Chemistry QR-1727, Manufacturing Use Product; Report No. GLP-2006-126. Unpublished study performed by Rohm and Haas Company, USA, and Safepharm Labs Ltd., UK submitted by Rohm and Haas Company, Philadelphia, PA. 170 pages
870.1100	Gilotti, Albert C. (2006), QR-1727: Acute Oral Toxicity Up and Down Procedure in Rats; Report No. 06RC-103. Unpublished study performed by MB Research Laboratories, and submitted by Rohm and Haas Company, Philadelphia, PA. 15 pages
870.1200	Gilotti, Albert C. (2006), QR-1727: Acute Dermal Toxicity/LD50 in Rats.; Report No. 06RC-115. Unpublished study performed by MB Research Laboratories and submitted by Rohm and Haas Company, Philadelphia, PA. 27 pages

OPPTS Guideline Ref. Number	Study Title
870.1300	Kirkpatrick, Daniel T. (2006), Acute Inhalation Toxicity Study of QR-1727 in Albino Rats; Report No. 06RC-118. Unpublished study performed by WIL Research Labs, LLC and submitted by Rohm and Haas Company, Philadelphia, PA. 151 pages
870.2400	Cerven, D.R. (2006), QR-1727: Acute Eye Irritation in Rabbits; Report No. 06RC-117. Unpublished study performed by MB Research Laboratories and submitted by Rohm and Haas Company, Philadelphia, PA. 24 pages
870.2500	Cerven, D.R. (2006), QR-1727: Acute Dermal Irritation in Rabbits; Report No. 06RC-116. Unpublished study performed by MB Research Laboratories and submitted by Rohm and Haas Company, Philadelphia, PA. 25 pages
870.2600	D.A. Hall. (2006), QR-1727: Guinea Pig Maximization Test (Magnusson-Kligman); Report No. 06RC-119. Unpublished study performed by MB Research Laboratories, and submitted by Rohm and Haas Company, Philadelphia, PA. 63 pages

Please feel free to contact me if there are any questions regarding this submission.

Sincerely,

James V. Hagan
Regulatory Affairs Manager
Rohm and Haas Company
Phone 215.641.7675
FAX 215.619.1654
jhagan@rohmhaas.com

/enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 19, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-378277
EPA File Symbol or Registration Number: 707-GRG
Product Name: SILVA DUR
EPA Receipt Date: 17-Apr-2007
EPA Company Number: 707
Company Name: ROHM & HAAS CO

JAMES V. HAGEN
ROHM & HAAS CO
ATTN: JAMES V. HAGAN
100 INDEPENDENCE MALL WEST
PHILADELPHIA, PA 19106-2399

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A54

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Please remit payment in the amount of: $ 4,200 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

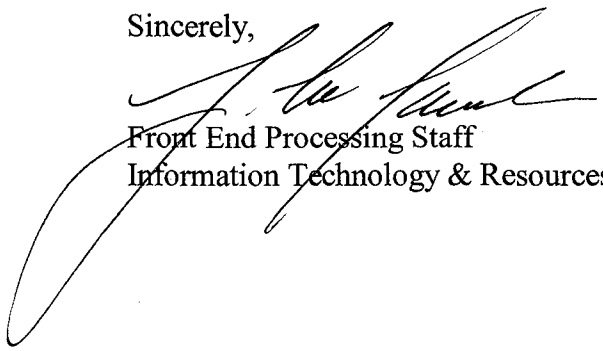
By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee

Ombudsman at (703) 308-6432.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division

15

Fee for Service

{8088740~

This package includes the following

- New Registration
- Amendment

✓ Studies? Fee Waiver?

✓ volpay % Reduction: ___

for Division

- (•) AD
- ( ) BPPD
- ( ) RD

Risk Mgr. 33

Receipt No. S- 808874

EPA File Symbol/Reg. No. 707-GRG

Pin-Punch Date: 4/17/2007

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A54

Granted: A54

Amount Due: $ 4200

Parent/Child Decisions:

Reviewer: Jam Date: April 19, 2007

Remarks:

Pages 135-143 *Confidential Statement of Formula may be entitled to confidential treatment*